APPENDIX TO

PETITION FOR WRIT OF CERTIORARI

No. _____

HILL DERMACEUTICALS, INC., Petitioner,

vs.

Rx SOLUTIONS, UNITED HEALTH GROUP, INC., and UNITED HEALTHCARE OF FLORIDA, INC., Respondents.

No.	Court	Title of Document	Docket No.	Date
1	11th Circuit Court of Appeals	Judgment & Opinion		12/17/08
2	11th Circuit Court of Appeals	Order denying Petition for Rehearing		1/21/09
3	U.S. District Court, Middle District of Florida, Orlando Div.	Order granting Motion to Remand	28 (Case No. 2032)	2/25/08
4	U.S. District Court, Middle District of Florida, Orlando Div.	Order denying Motion for Reconsideration of Order granting Motion to Remand	31 (Case No. 2032)	2/29/08
5	U.S. District Court, Middle District of Florida, Orlando Div.	Order denying Notice of Improper Removal, or in the Alternative, Plaintiff's Motion for Remand	34 (Case No. 330)	5/12/08

APPENDIX TO

PETITION FOR WRIT OF CERTIORARI

No. _____

HILL DERMACEUTICALS, INC., Petitioner,

vs.

Rx SOLUTIONS, UNITED HEALTH GROUP, INC., and UNITED HEALTHCARE OF FLORIDA, INC., Respondents.

No.	Court	Title of Document	Docket No.	Date
6	11th Circuit Court of Appeals	Petition for Rehearing		1/6/09
7	Circuit Court, 18th Judicial Circuit in and for Seminole County, FL	Complaint		11/16/07
8	U.S. District Court, Middle District of Florida, Orlando Div.	Plaintiff's, Hill Dermaceuticals, Inc.'s, Motion for Remand, Memorandum of Law, Alternative Request for Jurisdictional Discovery, and 3.01 Certification	18	1/29/08
9	U.S. District Court, Middle District of Florida, Orlando Div.	Amended Complaint	27 (Case No. 2032)	2/20/08

APPENDIX TO

PETITION FOR WRIT OF CERTIORARI

No. _____

HILL DERMACEUTICALS, INC., Petitioner,

vs.

Rx SOLUTIONS, UNITED HEALTH GROUP, INC., and UNITED HEALTHCARE OF FLORIDA, INC., Respondents.

No.	Court	Title of Document	Docket No.	Date
10	U.S. District Court, Middle District of Florida, Orlando Div.	Defendants' Motion and Memorandum of Points and Authorities for Reconsideration, or Alternatively, for this Court to Vacate its Remand order Dated February 25, 2008 and 3.01(G) Certification	29 (Case No. 2032)	2/26/08
11	U.S. District Court, Middle District of Florida, Orlando Division	Affidavit of Randall Coverman – Exhibit A to: Plaintiff, Hill Dermaceutical, Inc.'s Motion for Leave to Amend Complaint to Request Declaratory Judgment, Faster Hearing and Move Up Calendar Per Fed. Civ. 57, and More Specific Allegations to	39 (Case No. 330)	6/2/08

APPENDIX TO

PETITION FOR WRIT OF CERTIORARI

No. _____

HILL DERMACEUTICALS, INC., Petitioner,

vs.

Rx SOLUTIONS, UNITED HEALTH GROUP, INC., and UNITED HEALTHCARE OF FLORIDA, INC., Respondents.

No.	Court	Title of Document	Docket No.	Date
		Support Claims for Relief, with Attached Second Amended Complaint		

1

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 08-1333

Filed
U.S. Court of
Appeals
ELEVENTH
CIRCUIT
December 17, 2008
THOMAS K.KAHN

District Court Docket No
08-00330-CV-Orl-31-KRS

HILL DERMACEUTICALS, INC.,
a Florida corporation,
Plaintiff-Appellant,

versus

Rx SOLUTIONS,
a foreign corporation
a.k.a. Prescription Solutions Corporation,
UNITED HEALTH GROUP, INC.,
a foreign corporation,
UNITED HEALTHCARE OF FLORIDA, INC.,
Defendants-Appellees.

A True Copy - Attested
Clerk U.S. Court of
Appeals, Eleventh Circuit
By: s/_____
Deputy Clerk
Atlanta, Georgia

Appeal from the United States District Court
for the Middle District of Florida

J U D G M E N T

It is hereby ordered, adjudged and decreed that the attached opinion included herein by reference, is entered as the judgment of this Court.

Entered: December 17, 2008
For the Court: Thomas K. Kahn,Clerk
By: Gilman, Nancy

Issued as Mandate
Jan 29 2009
U.S. Court of Appeals
Atlanta, GA

Filed
U.S. Court of
Appeals
ELEVENTH
CIRCUIT
December 17, 2008
THOMAS K.KAHN

[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 08-1333
Non-Argument Calendar

D. C. Docket No. 08-00330-CV-Orl-31-KRS

HILL DERMACEUTICALS, INC.,
a Florida corporation,

Plaintiff-Appellant,

versus

Rx SOLUTIONS,
a foreign corporation
a.k.a Prescription Solutions Corporation,
UNITED HEALTH GROUP, INC.,
a foreign corporation,
UNITED HEALTHCARE OF FLORIDA, INC.,

Defendants-Appellees.

Appeal from the United States District Court
for the Middle District of Florida

(December 17, 2008)

Before TOJOFLAT, DUBINA and PRYOR, Circuit Judges

PER CURIAM:

Hill Dermaceuticals, Inc. appeals the dismissal of its amended complaint against Prescription Solutions, United Health Group, and United Healthcare of Florida. Hill challenges the denial of its motion to remand and the dismissal of its complaint that Prescription Solutions made false and misleading statements to third parties about a product of Hill, Derma-Smoothe. We affirm.

I. BACKGROUND

Prescription Solutions is a California-based pharmacy benefit manager that oversees prescription drug benefits for persons insured by managed care organizations. United Healthcare of Florida, an insurance company in Florida, contracted with Prescription Solutions to administer the drug formulary for its members. Both Prescription Solutions and United Healthcare are owned by United Health Group, a Minneapolis corporation.

Hill is a Florida corporation that manufactures and distributes Derma-Smoothe/FS body oil, a product marketed to treat eczema, atopic dermatitis, and psoriasis that affects between 50 and 90 percent of the body. Hill markets Derma-Smoothe as the only FDA-approved corticosteroid ointment for the treatment of systemic skin conditions. Derma-Smoothe is not on the formulary of Prescription Solutions.

In November 2007, Hill filed a complaint in a Florida court that alleged tortious conduct by Prescription Solutions, as an alter-ego or agent of United Healthcare, and their alleged parent companies, United Healthcare Company and Pacific Health Systems. Hill complained that Prescription Solutions made statements about Derma-Smoothe that constituted an injurious falsehood,

defamation, misleading advertising, and a deceptive and unfair trade practice. Hill alleged that all insurance companies were "required to cover Derma-Smoothe" and the suggestion that patients and physicians use an alternative medication constituted "false, deceptive, misleading and fraudulent information" about Derma-Smoothe.

Prescription Solutions and United Healthcare removed the action to federal court. The companies alleged that the district court had removal jurisdiction, 28 U.S.C. § 1441, based on a federal question, id. § 1331, and diversity of citizenship, id. § 1332. The companies also alleged that Hill fraudulently joined United Healthcare to defeat diversity jurisdiction.

Prescription Solutions and United Healthcare moved to dismiss the complaint for failure to state a claim and Hill moved to remand. The district court dismissed Hill's complaint without prejudice. Prescription Solutions and United Healthcare did not respond to Hill's motion to remand.

In the interim, Hill filed an amended complaint that named Prescription Solutions, United Healthcare, and United Health Group as defendants and accused the companies of the same tortious conduct alleged in the original complaint. Hill based its complaints on two letters alleged distributed by Prescription Solutions to unidentified parties regarding its payment for coverage of Derma-Smoothe. Hill alleged that the letters notified patients and physicians that Derma-Smoothe was not on the formulary of Prescription Solutions and was not covered by insurance unless a patient was intolerant to clobetasol, triamcinolone, and hydrocortisone. One letter allegedly stated:

> Based on the information provided by you or your physician, you do not meet the established medical necessity criteria or guidelines for [Derma-Smoothe] at this time. [Derma-Smoothe] is denied.

> The drug is not on our formulary, coverage requires a contraindication, failure or intolerance to the following formulary agents: triamcinolone, clobetasol, or hydrocortisone.

A second letter allegedly stated, "[Derma-Smoothe] is not on our formulary, coverage requires a contraindication, failure or intolerance to all of the formulary agents: clobetasol, triamcinolone, and hydrocortisone [is] required."

Five days later, the district court granted Hill's motion to remand. The district court granted the motion under "Local Rule.301(b)" because it was "unopposed." Prescription Solutions and United Healthcare moved for reconsideration, and the district court denied the motion.

United Health Group removed the action on the identical grounds stated by Prescription Solutions and United Healthcare in their motion to remove. Hill again moved to remand. After a hearing, the district court denied the motion to remand. The district court ruled that Hill had fraudulently joined United Healthcare in the amended complaint to defeat diversity of citizenship.

Hill later moved to amend the complaint to include a request for declaratory judgment. Hill attached to the second amended complaint an affidavit executed by Doctor Randall Coverman. Dr. Coverman stated that he had prescribed Derma-Smoothe and Prescription Solutions had denied coverage on the ground that Derma-Smoothe was not on the drug formulary. Dr. Coverman also stated that Prescription Solutions had notified his patient that Derma-Smoothe was a covered medication only if the patient had a "contraindication, failure or intolerance to" its "formulary agent(s). . . triamincinoline, clobetasol, or hydrocortisone." Dr. Coverman stated that the denial had "forced [him] into a position of having to choose a drug other than Derma-Smoothe . . . my drug of choice."

Prescription Solutions and United Healthcare moved to dismiss the second amended complaint for failure to state a claim. The district court found that "further amendments

would be futile" and dismissed Hill's complaint with prejudice.

II. STANDARDS OF REVIEW

We review de novo issues of subject matter jurisdiction. Bailey v. Janssen Pharmaceutica, Inc., 536 F.3d 1202, 1204 (11th Cir. 2008). We also review de novo the dismissal of a complaint for failure to state a claim and accept the allegations in the complaint as true and construe them in the light most favorable to the plaintiff. Glover v. Liggett Group, Inc., 459 F.3d 1304, 1308 (11th Cir. 2006). "We have jurisdiction to consider [the] denial of a motion to remand" after dismissal of a complaint with prejudice. Bailey, 536 F.3d at 1204. "As a general rule, an appellate court will not review a legal issue or theory not presented to the trial court, unless the issue is a pure question of law and the court's failure to consider it would result in a miscarriage of justice." Sierra Club, Inc. v. Leavitt, 488 F.3d 904, 912 (11th Cir. 2007) (quoting NAACP v. Hunt, 891 F.2d 1555, 1563 (11th Cir. 1990)).

III. DISCUSSION

Hill makes two arguments on appeal. First, Hill argues that the district court erred by denying the second motion to remand. Second, Hill argues that the district court erred when it dismissed the second amended complaint. We address each argument in turn.

A. The District Court Did Not Err When it Denied the Motion to Remand

Hill challenges the denial of its second motion to remand on three grounds. First, Hill argues that there is a single thirty-day period to remove an action and that United Health Group, who was served the complaint after the period elapsed, could not remove the action to federal court. Second, Hill argues that the district court lacked jurisdiction to consider the motion to remove filed by United Health Group because the district court had previously remanded the action to state court. Third, Hill

argues that the district court erred by finding that Hill fraudulently joined United Healthcare to defeat diversity jurisdiction. These arguments fail.

United Health Group timely removed the action to federal court. A notice is timely when it is "filed within thirty days after the receipt by the defendant . . . of a copy of the initial pleading setting forth the claim for relief upon which such action or proceeding is based . . . ." 28 U.S.C. § 1446(b). We recently adopted the "last-served defendant" rule, which accords each defendant thirty days to remove an action. Bailey, 536 F.3d at 1205. Hill filed an amended complaint that named United Health Group as a defendant on February 20, 2008, and United Health Group timely removed the action on March 5, 2008.

The district court also had jurisdiction to reconsider its earlier order to remand. Although a district court ordinarily may not reconsider an order remanding an action, 28 U.S.C. § 1447(d), that prohibition "applies only to cases remanded, pursuant to 28 U.S.C. § 1447(c), for lack of subject matter jurisdiction or defects in the removal procedure." First Union Nat'l Bank of Fla. v. Hall, 123 F.3d 1374, 1377 (11th Cir. 1997). The district court granted Hill's first motion to remand because it was unopposed, not for lack of jurisdiction or defects in procedure, so the court was "free to reconsider" its earlier decision. Id.

The record supports decision of the district court that Hill joined United Healthcare to defeat jurisdiction based on diversity of citizenship. To establish fraudulent joinder, a defendant bears a heavy burden to prove that "there is no possibility the plaintiff can establish a cause of action against the resident defendant . . . . " Pacheco de Perez v. AT&T Co., 139 F.3d 1368, 1380 (11th Cir. 1998) (quoting Crowe v. Coleman, 113 F.3d 1536, 1538 (11th Cir. 1997)). Hill offered two bases to hold United Healthcare liable for the statement of Prescription Solutions: first, Hill alleged that Prescription Solutions was an agent of and made the statements "on behalf of" United Healthcare. Hill's

complaint failed to establish that United Healthcare was an alter ego that dominated Prescription Solutions to "such an extent that [their] independent existence[] was in fact non-existent. . . ." Seminole Boatyard v. Christoph, 715 So. 2d 987, 990 (Fla. Dist. Ct. App. 1998). Under Florida law, the "[o]wnership by one corporation of all the stock of another corporation does not destroy the identify of the latter as a district legal entity; nor does the fact that the stockholders or officers in two corporations are the same persons operate to destroy the legal identify of either corporation." St. Petersburg Sheraton Crop. v. Stuart, 242 So. 2d 185, 190 (Fla. Dist. Ct. App. 1970). The facts alleged by Hill also did not establish that Prescription Solutions and United Healthcare had an agency relationship. For an agency relationship to exist, a principal must acknowledge that the agent may act for it and the agent must agree to act on behalf of and subject to the control of the principal. Goldschmidt v. Holman, 571 So. 2d 422, 424 & n.5 (Fla. 1990). Because the complaint did not contain facts to establish an alter ego or agency relationship, the district court was entitled to conclude that Hill fraudulently joined United Healthcare.

B. The District Court Did Not Err When It Dismissed The Amended Complaint.

Hill challenges the dismissal of his complaint on three grounds. First, Hill argues that under "liberal notice pleading standards" he alleged viable grounds for relief. Second, Hill argues, for the first time on appeal, that the district court was biased in favor of the defendants. Third, Hill argues that the district court "misread" and misapplied" the affidavit executed by Dr. Coverman. These arguments fail.

Hill's complaint fails to state a claim for relief. Hill complains that Prescription Solutions made false and defamatory statements about Derma-Smoothe that caused physicians and patients not to purchase the medication and that misled those third parties to believe that other

medications were appropriate substitutes. See Fla. Code § 817.41 (defining misleading advertising); Falic v. Legg Mason Wood Walker, Inc., 347F. Supp. 2d 1260, 1268 (S.D. Fla. 2004) (distinguishing injurious falsehood and defamation). The statements Prescription Solutions made about its coverage did not disparage or discount the efficacy of Derma-Smoothe. Prescription Solutions stated that patients could obtain coverage for the medication if other medicines did not resolve their skin conditions. Hill also complains of unfair trade practices, but its complaint fails to allege that Prescription Solutions competes with Hill for the sale or manufacture of medication for systemic skin conditions. See Third Party Verification, Inc. v. Signaturelink, Inc., 492 F. Supp. 2d 1314, 1325 (M.D. Fla. 2007); Alphamed Pharm. Corp. v. Arriva Pharm., Inc., 432 F. Supp. 2d 1319, 1353 (S.D. Fla. 2006). Hill complains that it was denied the opportunity to seek a declaratory judgment, but the dismissal of the amended complaint rendered the request moot. See Crown Media, L.L.C. v. Gwinnett County, Ga., 380 F.3d 1317, 1323 (11th Cir. 2004).

Hill's argument, raised for the first time on appeal, that the district court was biased also fails. "[B[ias sufficient to disqualify a judge must stem from extrajudicial sources . . . and must be focused against a party to the proceeding" to the degree that it calls into question the judge's impartiality. Hamm v. Members of Bd. Of Regents of State of Fla., 708 F.2d 647, 651 (11th Cir. 1983) (citation omitted). Hill complains about conclusions and derogatory comments of the court, but bias requires more than harsh comments or adverse rulings. Id.

The district court also did not misconstrue Dr. Coverman's affidavit. The district court "accept[ed] [Dr.] Coverman's statement as true," but correctly concluded that the affidavit did not support Hill's complaints against Prescription Solutions. Dr. Coverman stated that the medications covered under the formulary were not as effective as Derma-Smoothe and forced him to forego what

he believed to be a more effective treatment, but the affidavit did not, as Hill suggests, intimate that Prescription Solutions had "injured the reputation of Hill or its product or lead [Dr.] Coverman to believe that the Formulary Medications [were] as effective or useful as Derma-Smoothe." Dr. Coverman's affidavit did not evidence that the statements of Prescription Solutions were either false or disparaged Hill or the efficacy of Derma-Smoothe.

IV. CONCLUSION

The dismissal of the second amended complaint with prejudice is **AFFIRMED.**

A True Copy – Attested
Clerk U.S. Court of Appeals
Eleventh Circuit

s/

By:_____

Deputy Clerk
Atlanta, Georgia

2

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

FILED
U.S. COURT OF APPEALS
Jan 21 2009
THOMAS K. KAHN
CLERK

No. 08-13333-CC

HILL DERMACEUTICALS, INC.,
a Florida corporation,

Plaintiff-Appellant,

Versus

RX SOLUTIONS,
a foreign corporation
a.k.a. Prescription Solutions Corporation,
UNITED HEALTH GROUP, INC.,
a foreign corporation,
UNITED HEALTHCARE OF FLORIDA, INC.,
a Florida corporation,

Defendants-Appellees.

On Appeal from the United States District Court
for the Middle District of Florida

Before: TJOFLAT, DUBINA and PRYOR, Circuit Judges.

PER CURIAM:

The petition(s) for rehearing filed by Appellant is DENIED.

ENTERED FOR THE COURT:
s/

_____
United States Circuit Judge

3

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

HILL DERMACEUTICALS, INC.,
Plaintiff,

-vs- **Case No. 6:07-cv-2032-Orl-31GKJ**

RX SOLUTIONS, UNITED HEALTHCARE COMPANY, PACIFIC HEALTH SYSTEMS and UNITED HEALTHCARE OF FLORIDA,
Defendants.

_____/

ORDER

This matter comes before the Court on the Motion to Remand (Doc. 18) filed by the Plaintiff, Hill Dermaceuticals, Inc. ("Hill). The motion was filed on January 29, 2008. The deadline for a response was therefore February 15, 2008. No such response has been filed. Pursuant to Local Rule 3.01(b), the motion is therefore considered unopposed. Accordingly it is

ORDERED that this case is **REMANDED** to the Circuit Court for the Eighteenth Judicial Circuit, in and for Seminole County, Florida.

DONE and **ORDERED** in Chambers, Orlando, Florida on February 25, 2008.

s/ Gregory A. Presnell

_____

GREGORY A. PRESNELL
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel of Record

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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

HILL DERMACEUTICALS, INC.,
Plaintiff,

-vs- **Case No. 6:07-cv-2032-Orl-31GKJ**

RX SOLUTIONS, UNITED HEALTHCARE COMPANY, PACIFIC HEALTH SYSTEMS and UNITED HEALTHCARE OF FLORIDA,
Defendants.

_____/

ORDER

This case came on for consideration without oral argument on the following motion filed herein:

MOTION:	**MOTION FOR RECONSIDERATION OF REMAND ORDER (Doc. No. 29)**
FILED:	**February 26, 2008**
THEREON it is ORDERED that the motion is DENIED.	

DONE and **ORDERED** in Chambers, Orlando, Florida on February 29, 2008.

s/ Gregory A. Presnell

_____

GREGORY A. PRESNELL
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel of Record

5

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

HILL DERMACEUTICALS, INC.,

Plaintiff,

-vs- **Case No. 6:08-cv-330-Orl-31KRS**

RX SOLUTIONS, UNITED HEALTH GROUP, INC., and UNITED HEALTHCARE OF FLORIDA, INC.,

Defendants.
_____/

ORDER

This matter comes before the Court on the Notice of Improper Removal, or in the Alternative, Plaintiff's Motion for Remand (Doc. 7) filed by the Plaintiff, Hill Dermaceuticals, Inc. ("Hill"), and the response (Doc. 23) filed by Defendant United Health Group, Inc. ("UHG"). The Court has also considered the supplemental responses (Doc. 29, 30) filed by hill and UHG, respectively, pursuant to this Court's order of April 11, 2008 (Doc. 28).

I. Procedural Background

This is the second appearance of this dispute before this Court. Hill originally filed suit in state court on November 16, 2007. (Doc. 2 in Case No. 6:07-cv-2032-GAP-GJK (the "2032 Case")). The defendants in that suit included two

that are parties to this action—RX Solutions[1] and United Healthcare of Florida, Inc. ("United Healthcare")—and two apparently nonexistent entities, United Healthcare Company and Pacific Health Systems entities, United Healthcare Company and Pacific Health Systems. (Doc. 2 in the 2032 Case at 1). RX Solutions and United Healthcare asserted, as grounds for removal, that the case would necessarily require interpretation of labeling rules governed by the federal Good, Drug & Cosmetic Act ("FDCA") and prescription drug coverage issues governed by the Medicare Modernization Act ("MMA"), thereby establishing federal question jurisdiction. (Doc. 1 in the 2032 Case at 2). They also asserted that diversity jurisdiction existed, in that the amount in controversy exceeded $75,000 and the Plaintiff, a resident of Florida, was diverse from RX Solutions. (Doc. 1 in the 2032 Case at 5-6). They contended that the only Florida Defendant, United Healthcare, had been fraudulently joined to defeat diversity. (Doc. 1 in the 2032 Case at 6).

On January 17, 2008, RX Solutions and United Healthcare filed a Rule 12(b)(6) motion to dismiss (Doc. 14 in the 2032 case),which the Court granted on February 6. (Doc. 23 in the 2032 case). In the interim, on January 29, Hill filed a motion to remand (Doc. 18 in the 2032 case). Apparently believing that the dismissal of the complaint mooted the motion to remand, RX Solutions and United Healthcare failed to file a response. As a result, on February 25, the Court granted the Motion to remand as unopposed. (Doc. 28 in the 2032 case). On February 29, the Court denied reconsideration of the order granting the motion to remand. (Doc. 31).

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[1] In its papers, UHG identifies its co-defendant as "Prescription Solutions, Inc." rather than "RX Solutions". For the sake of consistency with previous orders, this order will refer to this party as "RX Solutions".

Hill had filed an amended complaint (Doc. 27 in the 2032 case) in this Court on February 20, 2008. In that document, Hill dropped United Healthcare Company and Pacific Health Systems as defendants and added UHG. UHG is diverse from Hill. On March 5, 2008, UHG removed the case back to this Court, citing the same bases as had been cited by RX Solutions and United Healthcare in the previous notice of removal: the existence of federal question jurisdiction due to preemption by the FDCA and MMA and the existence of diversity jurisdiction despite the allegedly fraudulent joinder of the no-diverse defendant, United Healthcare. (Doc. 1 at 3-9).

II. Standards

A. Removal

The general removal statute, 28 U.S.C. § 1441, provides in pertinent part that

> Except as otherwise expressly provided by Act of Congress, any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or defendants, to the district court of the United States for the district and division embracing the place where such action is pending. . . .
>
> Any civil action of which the district courts have original jurisdiction founded on a claim or right arising under the Constitution, treaties or laws of the United States shall be removable without regard to the citizenship or residence of the parties. Any other such action shall be removable only if none of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought.

28 U.S.C. § 1441(a), (b). The party seeking removal bears the burden of establishing federal jurisdiction. *See Diaz v. Sheppard*, 85 F.3d 1502, 1505 (11th Cir. 1996). Removal statutes are to be construed narrowly, with any

uncertainties to be resolved in favor of remand. *Burns v. Windsor Ins. Co.*, 31 F.3d 1092, 1095 (11th Cir. 1994). Removal procedure is governed by 28 U.S.C. § 1446, which provides, in pertinent part:

> The notice of removal of a civil action or proceeding shall be filed within thirty days after the receipt by the defendant, through service or otherwise, of a copy of the initial pleading setting forth the claim for relief upon which such action or proceeding is based, or within thirty days after the service of summons upon the defendant if such initial pleading has then been filed in court and is not required to be served on the defendant, whichever period is shorter.
>
> If the case stated the initial pleading is not removable, a notice of removal may be filed within thirty days after receipt by the defendant, through service or otherwise, of a copy of an amended pleading, motion, order or other paper from which it may first be ascertained that the case is one which is or has become removable, except that a case may not be removed on the basis of jurisdiction conferred by section 1332 of this title more than one year after commencement of the action.

28 U.S.C. § 1446(b). Section 1446(d) requires that "[p]romptly after the filing of such notice of removal of a civil action the defendant or defendants shall give written notice thereof to all adverse parties and shall file a copy of the notice with the clerk of the State court, which shall effect the removal and the State court shall proceed no further unless and until the case is remanded." An order remanding a case to the State court from which it was removed is not reviewable on appeal or otherwise, except that an order remanding a case to the State court from which it was removed pursuant to section 1443 of this title shall be reviewable by appeal or otherwise." 28 U.S.C. § 1447(d).

B. Fraudulent Joinder

When a plaintiff names a non-diverse defendant solely in order to defeat diversity jurisdiction, the district court must ignore the presence of the non-diverse defendant and deny any motion to remand the matter back to state court:

> The plaintiff is said to have effectuated a "fraudulent joinder," *see Crowe v. Coleman,* 113 F.3d 1536, 1538 (11th Cir. 1997), and a federal court may appropriately assert its removal diversity jurisdiction over the case. A defendant seeking to prove that a co-defendant was fraudulently joined must demonstrate either that: "(1) there is no possibility the plaintiff can establish a cause of action against the resident defendant; or (2) the plaintiff has fraudulently pled jurisdictional facts to bring the resident defendant into state court." *Id.* The defendant must make such a showing by clear and convincing evidence. *See Parks v. New York Times Co.,* 308 F.2d 474, 478 (5th Cir. 1962). *Henderson v. Wash. Nat'l Ins. Co.*, 454 F.3d 1278, 1281 (11th Cir. 2006).

III. Analysis

A. Effect of Previous Remand Order

Hill has raised a number of procedural arguments in favor of remand, such as an alleged failure of notice by the removing party, UHG. The Court disposed of these arguments in its order of April 11, 2008. (Doc. 28). Before addressing the substantive jurisdictional arguments raised in Hill's motion, the Court *sua sponte* raised the question of whether the granting of Hill's motion to remand in the 2032 Case—which attacked the preemption and fraudulent joinder arguments made by RX Solutions and United Healthcare in removing the 2032 Case—precluded UHG from subsequently making those same arguments. The Court required the parties to file supplemental briefs on "the issue of whether the remand order in the 2032 Case restricts UHG's ability to raise the federal-question and

fraudulent-joinder arguments it now seeks to make, either as law of the case or for some other reason." (Doc. 28 at 8).

UHG responded, in short, that although the Court had to treat the remand order in the 2032 case as law of the case, it should not exercise its discretion to do so, because it had not previously addressed the merits of the preemption or fraudulent joinder arguments. Rather, Hill's motion was granted because RX Solutions and United Healthcare failed to respond in time. For its part, Hill argued that the Court was, in effect, reconsidering the previous remand order, something it lacked jurisdiction to do. While agreeing that jurisdiction to reconsider the previous remand order is lacking, the Court rejects the contention that allowing UHG to raise these arguments is the equivalent of reconsidering the remand order in the 2032 Case, which was decided solely on timeliness grounds and to which UHG was not a party. The Court also finds no basis for exercising its discretion to treat the remand order in the 2032 Case as law of the case. Thus, the Court will address the substantive jurisdictional arguments in Hill's motion.

B. Fraudulent Joinder

The determination of whether a residential defendant has been fraudulently joined must be based upon the plaintiff's pleadings at the time of removal, supplemented by any affidavits and deposition transcripts submitted by the parties. *Pacheco de Perez v. AT&T Co.*, 139 F.3d 1368, 1380 (11th Cir. 1998). The Amended Complaint (Doc. 2)—the operative complaint at the time of the latest removal—is, simply stated, a rambling, ill-pleaded mess. So far as the Court can tell, the important allegations are these: Hill manufactures a product called "Derma-Smoothe/FS (Body Oil)" (henceforth, "Derma-Smoothe"). (Doc. 2 at 9). Hill alleges that Derma-Smoothe is the only drug approved to treat "widespread atopic dermatitis/eczema for patients

three (3) months and older with 50 percent to 90 percent of body involvement." (Doc. 2 at 8). United Healthcare is a health insurer that operates a health insurance plan in Florida. (Doc. 2 at 4). RX Solutions is the pharmacy benefits manager (or "PBM") for the United Healthcare. (Doc. 2 at 4). RX Solutions is the pharmacy benefits manager (or "PBM") for United Healthcare. (Doc. 2 at 4). UHG owns both RX Solutions and United Healthcare through several intervening wholly owned subsidiaries. (Doc. 23-2).

The focal point of the Amended Complaint is the undisputed allegation that RX Solutions has sent correspondence to unknown individuals[2] that included the following:

> Based on the information provided by you or your physician, you do not meet the established medical necessity criteria or guidelines for [Derma-Smoothe] at this time. [Derma-Smoothe] is denied. This drug is not on our formulary, coverage requires a contraindication, failure or intolerance to the following formulary agents: triamcinolone, clobetasol, or hydrocortisone.

(Doc. 2 at 10). According to Hill, the correspondence also included the following:[3]

> [Derma-Smoothe] is not on our formulary, coverage requires a contraindication, failure or intolerance to all of the formulary agents: clobetasol, triamcinolone, and hydrocortisone. Based on the clinical information

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[2] So far as the Court can tell, Hill has not filed a copy of this correspondence in this case. However, in its opposition, UHG did not dispute Hill's assertion that RX solutions had sent out the quoted passages.

[3] Hill alleges that RX Solutions sent two letters on this topic, but does not make it clear whether the quoted passages appear in one or both letters.

> provided, a trial on triamcinolone and hydrocortisone required.

(Doc. 2 at 10)

According to Hill, these passages "tell[] physicians and pharmacists that triamcinolone, clobetasol or hydrocortisone are safe to use on patients with up to 90 percent body involvement". (Doc. 2 at 10). This is not a reasonable interpretation of these passages. Hill does not allege that this correspondence was sent to (or regarding) a patient suffering from widespread atopic dermatitis/eczema, and the quoted passages does not even mention this condition. No ration reader could reach the absurdly specific conclusion Hill contends is embodied in the quoted text. And if they were to do so, the passages could not reasonably be interpreted as a slur on Hill's product. Even accepting Hill's interpretation of the quoted passages, RX Solutions would have been falsely characterizing the effectiveness of triamcinolone, clobetasol, or hydrocortisone, *not* the effectiveness of Derma-Smoothe. Nonetheless, based on these rather innocuous passages,[4] Hill contends that the public is being misled into thinking that there is an appropriate substitute for its product, causing Hill economic harm, irretrievably harming the value of its product, and jeopardizing patient safety, among a host of other alleged ills. (Doc. 2 at 12-13).

Hill attempts to bootstrap its unreasonable characterization of these passages into a number of causes of action. In its first count, titled "Preliminary Injunction/Temporary Restraining Order," Hill seeks to enjoin RX Solutions from sending any more of the allegedly

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[4] Hill also contends that RX Solutions has been communicating with healthcare providers by mail, trying to "coerce" them into changing their patients' prescriptions to something other than Derma-Smoothe. (Doc. 2 at 11). Hill offers no explanation as to how these communications, standing alone, might violate the law.

false and misleading letters referred to above.[5] (Doc. 2 at 15). In its second count, Hill alleges that in sending the correspondence, RX Solutions committed the tort of injurious falsehood. Under Florida law, the general rule is that

> One who, without a privilege to do so, publishes matter which is untrue and disparaging to another's property, in land, chattels or intangible things under such circumstances as would lead a reasonable man to foresee that the conduct of a third person as purchaser or lessee thereof might be determined thereby is liable for pecuniary loss resulting to the other from the impairment of vendability thus caused.

Falic v. Legg Mason Wood Walker, Inc., 347 F.Supp.2d 1260, 1268 (S.D.Fla. 2004) (quoting RESTATEMENT OF TORTS (SECOND) at § 624). As described above, despite Hill's efforts to mischaracterize the passages it quotes, the Amended Complaint does not allege that RX Solutions' correspondence was either untrue or disparaging to Hill's product. No reasonable reader of the quoted passages could reach such conclusions, and this is fatal to Hills' claim. This same failure dooms the claims raised in Hill's remaining counts: Count III (Defamation), Count IV (Misleading Advertising), Count V (Violation of FDUTPA), and Count VI (Product Defamation).[6] In short, Hill has failed to raise a single valid claim in the Amended Complaint.

When resolving a claim of fraudulent joinder, the district court must resolve all questions of fact in favor of the plaintiff. *Legg v. Wyeth*, 428 F.3d 1317, 1322-23 (11th

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[5] Hill does not specify the cause of action that allegedly entitles it to this remedy.

[6] Despite their differing titles, both Count III and Count VI allege harm to Hill resulting from disparagement of its product, rather than, for example, disparagement of Hill itself.

Cir. 2005). However, there must be some question of fact to be resolved. If the plaintiff, for example, fails to provide evidence to contradict the defendant's sworn assertions, the court cannot resolve the facts in plaintiff's favor based solely on the unsupported allegations in the complaint. Id. at 1323. In the instant case, Hill attempts to hold the non-diverse defendant, United Healthcare, responsible for the correspondence sent by RX Solutions. Charitably characterized, Hill offers two bases for doing so in the Amended Complaint: Hill alleges that RX Solutions sent the correspondence on behalf of UHF, and that the two parties are alter egos of one another. (Doc. 2 at 9-10).

However, even if one accepts them as true, Hill's alter ego allegations fail as a matter of law. Hill contends that

> Because UHG's employees make up over 50 percent of the Board of Directors for [United Healthcare], and a large portion of the directors for RX or Prescription Solutions, UHG also derives large percentages of profits from [United Healthcare], and in order to assure economies of scale, shares resources with [United Healthcare] and RX or Prescription Solutions. Consequently, [United Healthcare] and RX or Prescription Solutions are merely alter-ego corporations of UHG.

Doc. 2 at 9). Under Florida law, sharing of directors, resources and profits is not enough to make one corporation the alter ego of another. *See Seminole Boatyard, Inc. v. Christoph*, 715 So. 2d 987, 990 (Fla. 4th DCA 1998). In addition, UHG has produced affidavit evidence that the three Defendants do not share any directors at all, and that UHG does not employ any of the individuals serving as directors for United Healthcare or Prescription Solutions. (Doc. 23-2). Hill has not properly alleged or supported its claim that the Defendants are simply alter egos for one another.

Regarding agency, Hill's allegations are even more scant, consisting of conclusory assertions that RX Solutions sent the correspondence "on behalf of" United Healthcare. To establish agency under Florida law, a plaintiff must show that the principal acknowledged that the agent would act for it, that the agent accepted the undertaking, and that the principal controlled the agent's conduct. *Goldschmidt v. Holman,* 571 So. 2d 422, 424 (Fla. 1990). The Amended Complaint contains no such allegations, and Hill has not provided any evidence on this score. Thus, Hill has failed to raise a legitimate claim against RX Solutions for sending the correspondence or a legitimate basis for holding United Healthcare responsible for the actions of RX Solutions. As such, the Court finds that there is no possibility that Hill can establish a cause of action against United Healthcare, and the motion to remand must be denied.[7] *Henderson v. Washington Nat. Ins. Co.*, 454 F.3d at 1281. It is therefore

ORDERED that the Notice of Improper Removal, or in the Alternative, Plaintiff's Motion for Remand (Doc. 7) is **DENIED**.

DONE and ORDERED in Chambers, Orlando, Florida on May 12, 2008.

s/ Gregory A. Presnell

GREGORY A. PRESNELL
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel of Record
Unrepresented Party

[7] Because the Court concludes that diversity jurisdiction exists here, it does not reach UHG's argument that federal question jurisdiction also exists.

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UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

Appeals Case No.: 08-13333-CC

HILL DERMACEUTICALS, INC.,
Plaintiff/Appellant,
vs.
Rx SOLUTIONS, UNITED HEALTH GROUP, INC., and UNITED HEALTHCARE OF FLORIDA, INC.
Defendants/Appellees.
On Appeal from the United States District Court
Middle District of Florida
Case No.: 6:08-cv-330-31KRS

PETITION FOR REHEARING OF APPELLANT, HILL DERMACEUTICALS, INC.

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TABLE OF AUTHORITIES

Case Law

(Note: These pages will not correspond to text pages below but did correspond to text when submitted on 8 ½ x 11 paper as filed in the Eleventh Circuit Court of Appeals)

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J. Ring, B. Przebilla, and T. Ruzicka, editors, *The Handbook of Atopic Eczema*.....2

Howard I. Maibach, M.D. (citing R. Ramirez, Double-Blind Placebo-Controlled Cooperative Efficacy and safety study on psoriasis of the scalp comparing *Derma-Smoothe/FS (Scalp Oil)* to its vehicle). (Approval Study on File with the U.S. Food and Drug Administration).....4

INTRODUCTION

The United States Court of Appeals for the 11th Circuit has made several factual errors in its analysis of the *Hill v. Rx Solutions* December 17, 2008 Opinion it rendered. Because these errors are determinative in the outcome of this case, it is necessary to correct the Record and request a rehearing on these misconstrued issues of Law and Fact.

FDA/CMS Regulatory and Scientific Inaccuracies in the Court's Opinion Warrants Rehearing

First, according to the United States Food and Drug Administration an "oil" is not an "ointment". This Court continually throughout its opinion improperly refers to *Derma-Smoothe/FS Body Oil* ® as an "ointment". An "ointment" (is a solid) is medically defined by the FDA and all authorities as "semisolid preparation (usually containing a medicine) applied externally as a remedy or for soothing an irritation" or more precisely as "an ointment base consists of white petrolatum and stearyl alcohol, propyl glycol emulsified and preserved with paraben." *Derma-Smoothe/FS* is an "oil" (a liquid) a naturally occurring peanut oil, refined and tested to ensure that peanut protein (the substance that is responsible for peanut allergic response in individuals) is 0.5% or a negligible amount for patient safety.

This is an extremely important point in the legal analysis of this case because none of the other products that Rx Solutions would have doctors substitute is an oil. Therefore, they are improper as substitutes for the Hill products. To understand the vast importance of this issue:

> [T]he vehicle[1] used in dermatological products is of the utmost importance in the safe and effective treatment of dermatologic diseases, as it affects

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[1] Vehicle refers to the delivery system of the pharmaceutical (i.e. oil, cream, ointment, etc.)

> dermatopharmacokinetics and the skin itself. The corticoid component affects only the inflammatory process. So vital is the role of the vehicle in the safety of dermatologic drugs that the same corticoid, in the same strength and concentration, can be classified as mid-potency in one delivery system and a super potency in another simply by changing the vehicles.[2]

(Dkt. 39-2 at 9 [¶¶ 25, 26, 27, 28])

The other corticosteroid therapies suggested have great potential to cause adrenal suppression as stated in their labeling.[3] Therefore, this Court's misclassification of *Derma-Smoothe/FS®* as an "ointment", led to the erroneous conclusion that the ointments and *Derma-Smoothe/FS ® Oils* are interchangeable.

The issue present is one of safety. To correct the Record it is necessary to point out that *Derma-Smoothe/FS ® (Body Oil)* and *Derma-Smoothe/FS® (Scalp Oil)* are two separate and distinct products. They both happen to be oils, but their FDA indications (the diseases they are approved to be used on) are entirely different. The scalp oil is indicated for psoriasis. The Body Oil is indicated for atopic dermatitis/eczema. In order to decide this issue, this Court must consider that the FDA approves each pharmaceutical for specific uses on specific diseases. The drugs Rx Solutions suggests substituting are specifically indicated for neither. While doctors may choose to use a drug out of label indication, they cannot be forced to do so. This "forcing" of the issue interferes with the doctor/patient relationship. The reason *Derma-Smoothe /FS ® Body Oil* is indicated (approved by the FDA) for use on over 50 to 90% of the body (in each treatment) and *Derma-*

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[2] J. Ring, B. Przebilla, and T. Ruzicka, editors, *The Handbook of Atopic Eczema.*

[3] *See Clobetasol Label Warnings as approved by the FDA*

Smoothe/FS ® Scalp Oil is approved for single overnight treatment of four (4) or more hours while covered (with occlusion) is because of the properties of the oil vehicle the corticosteroid is contained within. The FDA approved this type of usage because of the safety provided by the oil. The conclusion of the FDA Pediatric Advisory Committee Meetings regarding the safety of topical corticosteroids, October 29 – 30, 2003 and March 24, 2004 stated:

> *Derma-Smoothe/FS® (Body Oil)* is the only topical corticosteroid clinically documented not to cause adrenal suppression in children 2 years and older, even when used over 90% of the body. [5] *Derma-Smoothe/FS® (Body Oil)* is approved for children and adults for the specific indication widespread atopic dermatitis/eczema >50% - 90% body involvement. This favorable feature of the drug is attributed to the vehicle and formulation, so that maximum benefit is derived, such as the ability of this vehicle to cover a larger surface area with a lesser amount of drug, its ability to hydrate and enhance penetration of the active component, and the stability of the molecule in the vehicle, among others. [4]

(Dkt. 27 at 6, 7 [¶¶ 21, 22, 23])

As to *Derma-Smoothe /FS ® Scalp Oil* the FDA reached the following conclusion:

> *Derma-Smoothe/FS® (Scalp Oil)* was approved for the indication of scalp psoriasis based on well-controlled, phase 3 clinical studies that involved once daily treatment of the whole scalp and occlusion with a shower cap that is part of the treatment and packaged with the product. *Derma-Smoothe/FS® (Scalp Oil)* is the only corticosteroid product has

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[4] FDA Pediatric Advisory Committee Meetings regarding the safety of topical corticosteroids, October 29 – 30, 2003 and March 24, 2004.

been tested and FDA-approved for use with this unique dosage form: once daily, over the entire scalp, with occlusion, for a minimum of 4 hours, unlike other products that are package label indicated to be used only on the affected areas.[5]

(Dkt. 39-2 at 9, 10 [¶¶ 25, 26, 30, 31, 32])

In essence, what do these scientific statements mean in simplified terms? The oil clinically appears to limit the absorption of the corticosteroid and prevents an over-dose. The potential over-dose from the substituted creams and ointments can create a serious condition called adrenal suppression. It clinically appears to be the oil's nature that prevents too much corticosteroid from entering the system.

The importance of this fact in deciding this appeal is: if the Court understands that an ointment is not interchangeable with an oil, then the ointments cannot be used to replace the oil. The FDA classifies these products differently for a reason. If this Court takes into account the position of the FDA, then the letters sent by Rx Solutions to Dr. Coverman and many other physicians, do in-fact, violate FDA regulations and indications and, in essence, provide misinformation to the doctors and their patients; thus, resulting in potential public safety issues and damage to Hill Dermaceuticals.

Second, Hill did not maintain that all insurance companies must cover *Derma-Smoothe /FS ® (Scalp Oil)* or *Derma-Smoothe/FS (Body Oil)*. The statement instead was much less broad and coincided strictly with FDA indications. In essence, the crux of the statement was that *Derma-Smoothe/FS® (Body Oil)* must be reimbursed if prescribed for a patient with greater than 50% to 90% body

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[5] Howard I. Maibach, M.D. (citing R. Ramirez, Double-Blind Placebo-Controlled Cooperative Efficacy and safety study on psoriasis of the scalp comparing *Derma-Smoothe/FS (Scalp Oil)* to its vehicle). (Approval Study on File with the U.S. Food and Drug Administration.)

involvement and for pediatric patients below the minimum age requirements for the drugs Rx Solutions mandates as substitutes. This is due to the fact that the FDA clearly prohibits the "Rx Solution substitute drugs" from use on patients with 50% to 90% body involvement and pediatrics under the age of 12 in specific instances like Clobetasol. Thus, the argument is that insurers must pay for the drugs when there is no substitute drug as in the specific indications and uses mentioned above. Section 1860D-4(b) of the Social Security Act. Law at ¶ 2261D (¶ 111).

The trial judge did not understand this concept and now this Court has misconstrued this FDA and the Centers for Medicare and Medicaid (CMS) concept for its regulation as well. The concept is a simple one: if no other drug is indicated and the doctor prescribes the only drug indicated, then the Medicare Part D funded provider has to reimburse for it. They may or may not be required to put it on formulary, but they have to reimburse for it. Section 1860-D-4(b) of the Social Security Actg. Law at ¶ 2261D. This section of the Act as amended for Part D states:

> [The Insurer] must take into account, whether including in the formulary or on a tier of the formulary particular covered Part D drugs that have therapeutic advantages in terms of safety and efficacy. Id.

This is the issue in this case. From this Court's opinion, 2008 W.L. S237155 *1, it is evident that a rehearing is necessary to correct the factual determinations in the Record. The confusion of "formulary" with "reimbursement", the confusion surrounding ointments and oils being equivalent and interchangeable and the confusion surrounding the specific indications where reimbursement is required mandates a rehearing and correction of the Record.

Incorrect Procedural Determinations by Appellant Court Warrant Rehearing

The issues remain as follows:

1. Ordered as moot the Motion to Amend to add the Second Amended Complaint for Declaratory Judgment in Count I, even though the declaratory relief claim was filed BEFORE the case was dismissed (as part of the Amended Complaint). (Dkt. 39 filed 6/2/08.) This Court erred in its factually incorrect finding that the Motion to Amend (in accordance and timely under the Case Management Order) was prior to the improper dismissal by the lower court. (Dismissed 6/5/08, Dkt. 40)

2. The wrongful Removal to federal court by a latter served defendant under unique facts of this case which distinguishes it from prior precedent. *Bailey v. Janssen Pharmaceutica, Inc.*, 536 F.3d 1202 (11th Cir. 2008).

3. The matter that the Defendants have improperly substituted inappropriate, non-indicated, non-generically approved drugs for Hill Dermaceuticals, Inc.'s (hereinafter Hill) *Derma-Smoothe/FS® (Scalp Oil)* and *Derma-Smoothe/FS® (Body Oil)*. Whereas these Hill products have no approved generic substitution and the Defendants have blatantly violated their obligation to reimburse for Hill's pharmaceuticals under the Medicare Prescription Drug, Improvement and Modernization Act of 2003, as amended, Part D, 2006, Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 42 U.S.C.) (hereinafter "Medicare Modernization Act, Part D" or "MMA, Part D") and Section 465.025, Fla. Stat. These Defendant managed care companies improperly refused to reimburse for products like Hill's, which have no generics or therapeutic equivalent drugs, regardless if these drugs are on Defendant's captive formulary.

4. The fact that this Court did not even comment on the Defendants charging the United States Government and poor elderly citizens $68 for a $48 product (exorbitant profits for United Health Group).

5. This Court misread the Coverman Affidavit because it did not correctly construe the science and FDA

regulation and approval process for specific indications. The Court improperly misread the "misled" requirement and virtually ignored the Plaintiff's argument that the doctor, despite the fact that he was not misled, was coerced into prescribing another inappropriate drug or forced his patient to have to pay cash for the medication, and misleading was not necessary to state a claim of relief.

6. The Trial Court never granted discovery on the "alter ego" or "agency" issue.

Argument on These Rehearing Issues

1. Hill served its Amended Complaint with a claim for a declaratory judgment, and the District Court, in-turn, dismissed with prejudice Hill's Amended Complaint, and ordered as moot the Motion to Amend to add the Second Amended Complaint for declaratory judgment (Dkt. 40, Case No. 330; V. II, R. 18), stating in its claim that a substitution by another pharmaceutical that is not indicated for use in that manner is a clear violation of the law, 21 C.F.R. 320.1(c) and 465.025, Fla. Stat. It is not possible for the Court to arrive at the correct determinative outcome, if this Court has not clarified that United Health's Policies are in violation of these laws and the MMA. Section 1860D-4(b) of the Social Security Act law at ¶ 2261D.

This Court also confused the timing issue. The claim for a declaratory judgment (filed June 2, 2008, Dkt. 39) was made prior to the dismissal (June 5, 2008, Dkt. 40); therefore, it cannot be dismissed as "moot".

2. First Served Defendant versus Last Served Defendant.

The Circuit Courts have decided this issue in only five (5) Circuits (Fourth, Fifth, Sixth, Eighth, and Eleventh) and are divided on the issue. The United States Supreme Court has not ruled on the issue yet to resolve this disparity between the Circuits. The danger in this division of opinion is "forum shopping".

In cases with multiple defendants, there is a split in authority--unresolved between the Circuits--on whether the thirty-day period to file, or join in, a notice of removal begins to run on the day of service on the first-served or last-served defendant. *United Computer Systems, Inc. v. AT & T Corp.,* 298 F.3d 756, 763 n. 4 (9th Cir.2002) (declining to adopt the first-served rule or the last-served rule). While *Bailey* stands as precedent in this Circuit and is outcome determinative in this case, it can arguably be stated with a great deal of certainty that the outcome of this case would be differently decided in a "first served" Circuit. I would argue that a definitive determination on the first and last served rule has yet to be established and challenge the validity of "split-circuit" rulings. *Bailey v. Janssen Pharmaceutica, Inc.,* 536 F.3d 1202 (11th Cir. 2008).

Middle District of Florida Rule 3.01(b) requires any party opposing a motion to respond within an appropriate period of time. Therefore, failure to file a response within the appropriate period of time is treated as acquiescence to the motion. Because Rx Solutions and United Healthcare did not respond within the deadline, this Court granted the Motion to Remand in the 2032 case. The original Motion to Remand clearly stated that a federal question was not at issue, that the Medicare Modernization Act of 2003 does not pre-empt the state action as was made clear by the Middle District of Florida by Judge Jenkins in *Masey v. Humana, Inc., No.* 806cv1713T24EAJ, 2007 WL 2363077 (M.D. Fla. Aug. 16, 2007), and the removal was defective. By not opposing these statements, mainly that the removal was defective, the Defendants acquiesced that their removal was defective according to M.D.L.R. 301(b). See also, 28 U.S.C. 1331 and 1332.

3. The matter that the Defendants have improperly substituted inappropriate, non-indicated, non-generically approved drugs for Hill Dermaceuticals, Inc.'s (hereinafter Hill) *Derma-Smoothe/FS® (Scalp Oil)* and

Derma-Smoothe/FS® (Body Oil) has been extensively argued in the early portion of this document entitled "FDA/CMS Regulatory and Scientific Inaccuracies in the Court's Opinion Warrants Rehearing."

4. The fact that this Court did not even comment on the Defendants charging the United States Government and poor elderly citizens $68 for a $48 product (exorbitant profits for United Health Group) warrants a rehearing on its own. The Defendants have mischaracterized their compliance with the MMA by trying to reargue their case on issues different from those on appeal. The Defendants claim that "Hill's claim is particularly egregious because Rx Solutions, Part D formulary actually includes Hill's product as a covered medication" is misleading. What the Defendants have contrived in order to get around the MMA regulation and to violate the spirit of the law and its intent is to place all pharmaceuticals that are not on Tier 1 (common generic medications) or not on Tier 2 (preferred brand products), on their Tier 3 formulary. There are no constraints on their Tier 3 formulary and all products that are produced and FDA approved are included as such. However, this forces the United States Government and elderly patients to pay $68 for a $48 product. Section 1860D-4(b) of the Social Security Act law at ¶ 2261D.

5. This Court has factually and legally misinterpreted the Coverman Affidavit. That ruling came despite the fact that the District Court read the Coverman Affidavit to say Defendants could only have liability if they, in fact, "misled" a healthcare provider, and the healthcare provider admitted to being "misled", a/k/a committing medical malpractice, by improperly substituting for Hill's products these non-generic and non-therapeutic equivalents. Misleading was not necessary for potential liability of Appellees. The Court improperly misread the "misled" requirement and virtually ignored the Plaintiff's argument that the doctor, despite the fact that he was not misled, and filed a prior authorization form as the

insurance required, was coerced into prescribing another inappropriate drug or forced his patient to pay cash for the medication. In essence, the letters rejecting *Derma-Smoothe/FS® (Scalp Oil)* and *Derma-Smoothe/FS® (Body Oil)* as the appropriate treatment and coercing the prescribing physicians and pharmacists to substitute another less safe and inappropriate drug is a clear violation of the law and even more, an affront to appropriate public policy.

Dr. Coverman clearly stated in his affidavit, "Rx Solutions' denial forced me into a position of having to choose a drug other than *Derma-Smoothe/FS Scalp Oil*, my drug of choice. I would have had to prescribe medications for my patient, against my better judgment, that either 1) may cause adrenal suppression, as stated on the products' labeling; 2) are not indicated for scalp Psoriasis, and 3) have no safety data in their labeling. It is not a matter of whether or not Dr. Coverman was misled, but more importantly, did United Health Group violate the law and state to Dr. Coverman that the substitute drugs they suggested were interchangeable with *Derma-Smoothe /FS ® (Scalp Oil)* or *Derma-Smoothe /FS ® (Body Oil)*? This point should be of major consideration in a rehearing. Misleading was not a legal element of our claim and is not an element necessary for recovery.

6. The Trial Court never granted discovery on the "alter ego" or "agency" issue.

The Defendant stated that UHG does not operate nor conduct business in the State of Florida. However, UHG's corporate, SEC filings, and publicly disclosed statements say: UHG operates in all 50 states and internationally. (Exhibit "A", 2007 Quarterly Report from UHG, attached to Plaintiff Hill's Memorandum in Opposition to Defendant, UHG's Motion to Dismiss, Dkt. 25, Case No. 330.) The question then becomes in this proceeding is UHG misleading its members, the public or the federal District Court when it states it does not do

business in Florida? UHG in its Form 10-Q filed with the Securities and Exchange Commission giving its quarterly report which provides a continuing view of the company's financial position filed November 1, 2007, clearly states:

> Through our Prescription Solutions Pharmacy Benefit Management (PBM) business, revenues are derived both by products sold and administrative services.

UHG, again, in its 10-Q, (see Exhibit "B" attached to Plaintiff's Hill's Memorandum in Opposition to Defendant, UHG's Motion to Dismiss, Dkt. 25, Case No. 330), states that:

> In the event a Court were to determine that our PBM business acts as a fiduciary under ERISA, we can be subject to claims for alleged breaches of fiduciary obligations in implementation of formularies, preferred drug listings, and drug management programs, contracting network practices, specialty drug distributions and other transactions. www.unitedhealthgroup.com.

One of the most important errors that the federal District Court made is that it did not allow discovery. Without discovery, despite much preliminary evidence showing that UHG may very well either operate in Florida or have an agency relationship with United Health Care of Florida, it was impossible to prove the existence of this relationship.

Conclusion

Derma-Smoothe/ FS ® is a unique product with no authorized substitutes. The MMA requires Part D Medicare funded insurers to reimburse for products without substitutes. The correspondence between Rx Solutions and Dr. Coverman clearly indicates that Rx believes there is a substitute for *Derma-Smoothe /FS* ® and informs doctors to inappropriately substitute for it.

Whereas, Hill requests this Court to Rehear this matter and correct these inaccuracies in the Record which will alter this Court's original incorrect opinions and inaccuracies.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 6, 2009, I served the foregoing with the Clerk of the Court by Federal Express/Overnight Mail (an original and three copies) to: Thomas K. Kahn, Clerk, U.S. Court of Appeals for the 11th Circuit, 56 Forsyth Street, N.W., Atlanta, Georgia 30303; and served a copy by U.S. Mail to: Edmund O. Loos III, Esquire, and Amanda L. Chapman, Esquire, GREENSPOON MARDER, P.A., Capital Plaza I, Suite 500, 201 East Pine Street, Orlando, FL 32801 and to William A. Davis, Esquire, and Noam B. Fischman, Esquire, MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C., 701 Pennsylvania, NW, Washington, DC 20004-2608.

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IN THE CIRCUIT COURT OF FLORIDA, EIGHTEENTH JUDICIAL CIRCUIT, IN AND FOR SEMINOLE COUNTY

CASE NO. 2007CA-03772-16-L

HILL DERMACEUTICALS, INC., a Florida corporation,

Plaintiff,

vs.

Rx SOLUTIONS, also known as PRESCRIPTION SOLUTIONS CORPORATION, a foreign corporation, UNITED HEALTHCARE COMPANY, PACIFIC HEALTH SYSTEMS, a foreign corporation, and UNITED HEALTHCARE OF FLORIDA, a Florida corporation,

Defendant.

_____/

COMPLAINT

The Plaintiff, HILL DERMACEUTICALS, INC., a Florida corporation (hereinafter referred to as "HDI"), by and through its undersigned counsel, hereby sues the Defendants, Rx SOLUTIONS (hereinafter "Rx Solutions"), also known as PRESCRIPTON SOLUTIONS CORPORATION (hereinafter "Prescription Solutions"), a foreign corporation, UNITED HEALTHCARE COMPANY (hereinafter "United Healthcare"), a foreign corporation,

PACIFIC HEALTH SYSTEMS, a foreign corporation (hereinafter "Pacific Health") and UNITED HEALTHCARE OF FLORIDA (hereinafter "United Healthcare of Florida"), a Florida licensed health insurer, (herein known as the "Defendants") and alleges the following:

GENERAL ALLEGATIONS

JURISDICTION, VENUE AND PARTIES

1. This is an action for damages that exceed Fifteen Thousand Dollars ($15,000.00), exclusive of interest, costs, and attorney's fees.

2. At all times material hereto Plaintiff, HDI, is a Florida corporation, with its principal place of business in Seminole County, Florida, and legally organized, created and established under the laws of the State of Florida, and a citizen of Florida. At all times material hereto HDI distributed and marketed Derma-Smoothe/FS® (fluocinolone acetonide) 0.01% Topical Oil (Body Oil).

3. At all times material hereto the Defendant, Rx Solutions, also known as Prescription Solutions, is a wholly owned subsidiary of United Healthcare doing business in Florida through its wholly owned United Healthcare of Florida affiliate, a Florida corporation.

4. At all times material hereto the Defendant, Pacific Health/United Healthcare, is now merged under United Healthcare, doing business in Seminole County, Florida, and it's a wholly owned and operated subsidiary United Healthcare of Florida, maintaining registered agents in Florida. In addition, United Healthcare of Florida insures the State employees of the State of Florida, a large amount of them in Seminole County, Florida.

5. At all times material hereto, the Defendant, Rx or Prescription Solutions, is a wholly owned subsidiary of United Healthcare, doing business in Florida through its wholly owned subsidiary United Healthcare of Florida, a Florida corporation. Additionally, United Healthcare is the parent organization for which Rx or Prescription Solutions prepares the formulary for and administers the pharmacy

benefit management services to the lives insured of the employees of the State of Florida, and United Medicare Rx, a Medicare PDP Prescription Drug Plan ("PDP"), operated in Florida by United Healthcare of Florida.

THE Rx SOLUTIONS/PRESCRIPTION SOLUTIONS/ PACIFICARE HEALTH SYSTEMS/ UNITED HEALTHCARE COMPANY DEFENDANTS

6. The Defendants conduct their business in Florida, as well as nationwide through various subsidiaries in a myriad of states. The Defendants provide pharmacy benefit management services, a Medicare Part D Prescription Drug Plan ("MMA Part D PDP") to persons in the State of Florida in their own name and through their wholly owned subsidiaries. The parent organization, United Healthcare, as part of the integrated healthcare systems United Healthcare of Florida insures the employees of the State of Florida.

7. The Defendants advertise and provide information to healthcare providers, their plan participants and the general public through the Internet. The Defendants' website is accessible by Florida residents and to residents in Seminole County, Florida. The Defendants intend and expect Florida residents to access and utilize their websites, in Florida.

8. The Defendants insure patients in Seminole County, Florida and throughout the State of Florida, including State employees based in Seminole County, Florida, most notably at the Seminole County Courthouses. United Healthcare and United Healthcare of Florida also operates many plans whose pharmacy benefit manager is Rx or Prescription Solutions, a wholly owned subsidiary of United Healthcare. As integrated health care companies, the Defendants operate and have operated, prescription drug networks, pharmacies and mail order pharmacies in Florida under the name of Prescription Solutions and United Healthcare of Florida, both United Health Group Companies and in the name of United Healthcare Rx

Medicare Prescription Drug Plan (formerly PacifiCare Plans Medicare Part D PDP.) Additionally, Prescription Solutions provides maintenance medications management services and formulary to the American Association of Retired Persons ("AARP") for their Prescription Drug Plans. The AARP has extensive members throughout Florida and throughout Seminole County. Each of the Defendants' network mail order pharmacies is licensed as a pharmacy under the laws of the State of Florida, as well as certain other states. Each of these mail order pharmacies is controlled by, and is an alter ego of, the Defendants.

9. The Defendants insure and provide prescription benefits for a vast number of patients who have contracted with United Healthcare of Florida for Medicare Rx Part D PDP, and Rx, as well as private care plans. The Defendant organizations are insuring patients and providing prescription benefits to lives under their insure in the State of Florida and in Seminole County, Florida. The Defendants operate a network of mail order pharmacies, where plan participants are directed and required to fill their maintenance prescriptions.

10. The Defendants intentionally avail themselves of the jurisdiction of the State of Florida by conducting extensive business in Florida including insuring patient lives and providing prescription benefit management and prescription reimbursement for those captured lives, dispensing prescriptions through their mail order pharmacies and their network pharmacies and providing PBM services to those entities. Defendants also operate, conduct, engage in, and carry on their business and business ventures outside of the State of Florida, but with the express intention and expectation that their business activities include communications to and within the State of Florida, as well as conducting advertising, sales and marketing within the State of Florida, and insuring the Florida State employees. These particular Defendants have also been marketing their businesses in

the State of Florida through various electronic means including but not limited to the Internet and website companies. As a result of all these activities, the Defendants derive substantial income from the State of Florida and from those insured in the State of Florida. United Healthcare of Florida derives 100% of its income from the State of Florida. Further, the Defendants, by and through their business activities and organizations, engage in substantial and not isolated activity within the State of Florida, including both intra-state and interstate commerce. Further, the Defendants have caused injury to HDI and its property within Florida from intentional acts and conducts arising outside of Florida.

11. Whether provided by a health plan, an employer, a government agency, or some other entity, millions of Americans have insurance coverage that includes a pharmacy benefit component, which provides payment for prescription drugs. This pharmacy benefit component is typically managed by a pharmacy benefit manager ("PBM"). The pharmacy benefit manager specializes in administering the pharmacy benefit in return for payment in some form by the provider of the pharmacy benefit. The Defendants are a pharmacy benefit manager health insurer and MMA Part D PDP operator as well as operator of many state and privately funded plans. According to their own website they provide pharmacy benefit management services in the State of Florida, including Seminole County, and insure the health of patients and act as a fully integrated health care company.

12. The Defendants themselves and through its mail order and traditional pharmacies network is engaged in the practice of pharmacy, health insurance and MMA Part D PDP's, has captured lives under control for prescription benefits, and is licensed to do so under the laws of various states, including Florida. As a Florida licensed pharmacy provider and health insurer the Defendant and its pharmacy network and mail order

pharmacy owes a duty to Rx or Prescription Solutions and United Healthcare of Florida plan participants, whose prescriptions they fill or arrange to be filled. Defendants and their network pharmacies employ licensed professional pharmacists, as well as licensed or certified pharmacy technicians, who perform or assist in performing professional pharmacy services for these Plan participants. Defendants and their network pharmacies and mail order pharmacies represent to Rx or Prescription Solutions clients (the entities providing the pharmacy benefit to the plan participants), plan participants and healthcare providers/prescribers that it will provide the same or similar pharmacy services performed by professional pharmacists at non-network pharmacies and contract to provide to their insured in private, public, and MMA Part D PDP patients access to medically necessary treatment and prescriptions.

HDI'S DERMA-SMOOTHE/FS® (BODY OIL)

13. HDI distributes and markets Derma-Smoothe/FS® (Body Oil), for all fifty States, including specifically Florida. This prescription drug is the only topical corticosteroid which has been proven safe and effective by the Food and Drug Administration ("FDA") for atopic dermatitis/eczema in both children (ages 2 and above), and adults with as much as 90% body involvement.

14. Derma-Smoothe/FS® (Body Oil) is the only low-potency topical corticosteroid that has been granted a full New Drug Approval by the Food and Drug Administration for the specific indication of atopic dermatitis/eczema, in both children (ages 2 and above) and adults with as much as 90% body involvement. As such, Derma-Smoothe/FS® (Body Oil) has no bioequivalent or therapeutic generic drug. Florida Statute 465.025 states biological or therapeutic inequivalence, if substituted would pose a threat to the public health. Using that criteria, substitution of a non-equivalent product in Florida by a licensed pharmacist is illegal.

15. Derma-Smoothe/FS® (Body Oil) is the only corticosteroid product shown not to cause adrenal suppression in patients afflicted with atopic dermatitis/eczema even when used over as much 90% of the body.

16. Derma-Smoothe/FS® (Body Oil) is the FDA's reference-listed drug as set forth in the Agency's Orange Book.[1] Additionally, said listing clearly shows there is no bioequivalent for this drug.

17. In order to obtain a New Drug Approval from the Food and Drug Administration for Derma-Smoothe/FS® (Body Oil), HDI incurred great time and expense to complete the requisite FDA safety and efficacy studies.

18. As there is no bio-equivalent or generic equivalent product approved by the FDA for Derma-Smoothe/FS® (Body Oil), Managed Care Organizations ("MCO's") are required to cover Derma-Smoothe/FS® (Body Oil) if they treat and/or cover atopic dermatitis/eczema patients. Therefore, Derma-Smoothe/FS® (Body Oil) is required to be a covered drug in plans managed by the Defendants when Derma-Smoothe/FS® (Body Oil) is prescribed for the treatment of atopic dermatitis/eczema. Florida Statutes 465.025 states biological or therapeutic inequivalence, if substituted would pose a threat to the public health. Otherwise, the Defendants are coercing pharmacists to illegally substitute an inequivalent product.

19. Furthermore, as there is no generic equivalent product approved by the FDA for Derma-Smoothe/FS® (Body Oil), any alternative prescription recommended is not the bioequivalent or therapeutic equivalent product to Derma-Smoothe/FS® (Body Oil) and cannot be substituted or represented as such. Any action to substitute this product is illegal because it constitutes a misrepresentation

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[1] See listing in the Orange Book – http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm.

of HDI's product and illegally modifies and interferes with the prescribed treatment of the doctor.

20. It is inappropriate and illegal for any MCO to suggest any alternatives that are not bioequivalent or therapeutic equivalents of Derma-Smoothe/FS® (Body Oil) and/or to refuse to cover HDI's medication. No other fluocinolone acetonide formulation or, for that matter, any other topical corticosteroid can legally be interchanged and dispensed when a prescription is written for Derma-Smoothe/FS® (Body Oil).

21. Any actions which result in the denial of coverage for Derma-Smoothe/FS® (Body Oil), in essence, tells pharmacists not to fill a Derma-Smoothe/FS® (Body Oil) prescription, but instead to illegally substitute a product or products which the FDA has not approved for this type of disease and treatment. Such substitutions result in a modification and disruption of the doctor-prescribed treatment by an MCO, which is clearly illegal under Fla. Stat. 465.025.

STATEMENT OF THE CASE

22. On or about February 21, 2007, HDI learned that the Defendants were improperly and illegally informing patients who were appropriately prescribed Derma-Smoothe/FS® (Body Oil) by their healthcare providers that there existed the medically inappropriate alternatives of Fluocinolone Acetonide 0.01% creams and lotions to treat atopic dermatitis/eczema. Moreover, at said time, HDI learned that the Defendants were denying coverage of Derma-Smoothe/FS® (Body Oil), yet were willing to cover what were being incorrectly termed a "generic substitution" for the brand name drug. Additionally, Defendants have been communicating with healthcare providers and notifying them by mail directly in an effort to coerce them to change their patients' prescriptions from the product Derma-Smoothe/FS® (Body Oil).

23. MCO's are required to cover Derma-Smoothe/FS® (Body Oil) if they treat and/or cover atopic dermatitis/eczema. There are no generic equivalent products approved by the FDA for Derma-Smoothe/FS® (Body Oil). The action taken by the Defendants to deny coverage forces an illegal substitution which the FDA has not approved for this type of disease and treatment.

24. The Defendants have inappropriately suggested alternatives that are not the bioequivalent or therapeutic equivalents of Derma-Smoothe/FS® (Body Oil) and inappropriately denied coverage of HDI's medications.

25. The Defendants, and their wholly owned network pharmacies, have disseminated and continue to disseminate false, deceptive, misleading and fraudulent information to Florida healthcare providers, to the Defendants' Florida plan participants regarding HDI's products, Derma-Smoothe/FS® (Body Oil), as well as throughout the United States. Specifically, on Derma-Smoothe/FS® (Body Oil) prescriptions filled or arranged to be filled by the Defendants and/or their network or mail order pharmacies, the Defendants and/or their network or mail order pharmacies are providing inaccurate information. The Defendants are suggesting alternatives that are not the bioequivalent or therapeutic equivalents of Derma-Smoothe/FS® (Body Oil) and is refusing to cover HDI's medications.

26. The information being disseminated by the Defendants is false and has great potential to harm patients, as they are intentionally being deterred from purchasing and/or using Derma-Smoothe/FS® (Body Oil). In light of the false information, patients will use less safe and efficacious products.

27. As a result of the Defendants' substitution, HDI is being and has been economically damaged, as well as having had the value of its products irretrievably harmed. The Defendants have damaged HDI economically

and have disparaged HDI's products' good name and reputation.

28. More importantly, the Defendants have jeopardized patient safety by denying coverage of Derma-Smoothe/FS® (Body Oil). Neither patients nor physicians can be forced to try other drugs that are unproven, potentially dangerous, and/or not effective in treating atopic dermatitis/eczema, merely because other drugs are covered by Rx or Prescription Solutions, and United Health Medicare Rx, United Healthcare of Florida and United Healthcare Companies' integrated healthcare system.

29. As Derma-Smoothe/FS® (Body Oil) is the only product for the treatment of atopic dermatitis/eczema in patients with up to 50% to 90% of their body involved, HDI expects its products to be placed on the Defendants' formularies' preferred list immediately as a first line therapy.

30. As a direct and proximate result of the Defendants' unlawful, deceptive, and misleading labeling and/or advertising, HDI has suffered and continues to suffer irreparable loss and injury.

31. As a direct and proximate result of Defendants' unlawful, deceptive, and misleading advertising, HDI's good name and reputation have been libeled, slandered, and/or disparaged. Specifically, the Defendants have and continue to disseminate and/or publish false statements that induce potential Derma-Smoothe/FS® (Body Oil) users and/or purchasers to believe that Derma-Smoothe/FS® (Body Oil) is not the only drug available for the treatment of atopic dermatitis/eczema in pediatrics and adults, and that there are generic versions of said drug. This has resulted in economic damages to HDI, including but not limited to, lost sales, lost profits, and diminution of value of its intellectual property ownership of the NDAs.

32. All conditions precedent to the filing of this lawsuit have been satisfied, met, or waived.

COUNT I
PRELIMINARY INJUNCTION / TEMPORARY RESTRAINING ORDER

33. HDI realleges and incorporates by reference the allegations contained in paragraphs 1 through 32 of the Complaint as if fully set forth herein.

34. This is an action for temporary injunctive relief.

35. Defendants have disseminated and/or published and continue to disseminate and/or publish false, misleading, deceptive, libelous and/or defamatory statements, advertisements, and/or representations regarding HDI's product, Derma-Smoothe/FS® (Body Oil).

36. In light of the Defendants' tortious acts, HDI suffers and will continue to suffer economic damages and, more importantly, damages to its reputation and intellectual property for which there is no adequate remedy at law. The value of HDI's products and its innovative reputation will continue to be diminished by the Defendants' actions.

37. Despite HDI's requests to cease and desist this continuing tortious activity, Defendants continue to disseminate and/or publish these false, misleading, and defamatory statements.

38. Unless Defendants are restrained and enjoined from disseminating and/or publishing this false, misleading, deceptive, libelous and defamatory information regarding Derma-Smoothe/FS® (Body Oil), HDI will continue to suffer permanent, severe and irreparable harm that will lead to the complete and unfounded destruction of its reputation in Florida and nationally.

39. HDI has a clear legal right to relief on its claims for damages based on Defendants' violations of various state causes of action including, but not limited to, Florida's Deceptive and Unfair Trade Practices Act,

misleading advertising (Florida Statutes § 817.41), injurious falsehood, and defamation.

40. The issuance of an injunction will serve the public interest as it will prevent the dissemination of false and misleading information that could lead to the harm of Florida residents, as this information will result in the prescription, purchase and use of drug products without the proven safety and efficacy record of Derma-Smoothe/FS® (Body Oil) for their specific indications. In addition, in light of Defendants' tortious acts, as outlined above, patients will forego or avoid the purchase and/or use of Derma-Smoothe/FS® (Body Oil), which use would likely be beneficial to their specific disease entity.

41. Defendants have been provided more than adequate notice to cease and desist their tortious activities of dissemination. Upon information and belief, every day patients using the Defendants' pharmacy benefit program are obtaining false, misleading, deceptive, and/or defamatory information regarding Derma-Smoothe/FS® (Body Oil). As such, Defendants' dissemination of this false information will lead to inappropriate treatment, and will endanger the physical well-being of Florida residents.

42. Moreover, this will lead to the diminution in value of Derma-Smoothe/FS® (Body Oil), and the devaluation of HDI's stellar reputation in the Florida and national pharmaceutical communities.

WHEREFORE, HDI respectfully requests this Court temporarily and permanently enjoin the Defendants from disseminating false, misleading, deceptive, libelous, and/or defamatory information outlined above regarding Derma-Smoothe/FS® (Body Oil).

COUNT II
INJURIOUS FALSEHOOD

43. HDI realleges and incorporates by reference the allegations contained in paragraphs 1 through 32 of the Complaint as if fully set forth herein.

44. This is an action for injurious falsehood.

45. Defendants have disseminated and continue to disseminate false, misleading, deceptive, and/or defamatory information regarding Derma-Smoothe/FS® (Body Oil). Specifically, regarding Derma-Smoothe/FS® (Body Oil) prescriptions that the Defendants fill or arrange to fill or reimburse or arrange to reimburse for the Defendants have improperly suggested alternatives that are not bioequivalent or therapeutic equivalents of Derma-Smoothe/FS® (Body Oil).

46. Any suggestion that there exists any generic equivalent of Derma-Smoothe/FS® (Body Oil) constitutes an injurious falsehood on the part of the Defendants, which has caused damage to HDI and loss of income in Derma-Smoothe/FS® (Body Oil).

47. The Defendants' affirmative suggestion of a non-indicated equivalent contains false information, as published clinical studies indicate.

48. This false, misleading and/or defamatory information was disseminated and/or communicated to third persons, including, but not limited to, Florida residents participating in the Defendants' various pharmacy benefit plans.

49. Defendants knew or should have known that the false, misleading, and/or defamatory information was likely to influence Florida residents, namely prospective healthcare providers/prescribers and/or users of Derma-Smoothe/FS® (Body Oil).

50. The false, misleading, and/or defamatory information that Defendants have disseminated regarding each prescription for Derma-Smoothe/FS® (Body Oil) has played and continues to play a material and substantial role in inducing Florida residents, and residents throughout the country, namely prescribers, patients, and/or Defendants' pharmacy benefit plan participants, to purchase and/or use drugs other than Derma-Smoothe/FS® (Body Oil), and/or come to the false belief that there are

alternatives to Derma-Smoothe/FS® (Body Oil). This conduct by Defendants have been intentional, willful, and undertaken with malice.

51. As a direct and proximate result of the publication, dissemination and/or communication of Defendants' false, misleading, deceptive and/or defamatory statements, HDI has suffered compensatory and punitive damages, including but not limited to general, special, consequential, incidental, lost profits, lost revenues, diminution in the value of the product, and the devaluation of HDI's reputation.

COUNT III
DEFAMATION

52. HDI realleges and incorporates by reference the allegations contained in paragraphs 1 through 32 of the Complaint as if fully set forth herein.

53. This is an action for defamation.

54. The Defendants are affirmatively disseminating that there are other fluocinolone acetonide formulations and other corticosteroid products that demonstrate the bioequivalence and/or therapeutic equivalence to Derma-Smoothe/FS® (Body Oil).

55. The Defendants have specifically by their actions implied that there are bioequivalent and/or therapeutic equivalents to Derma-Smoothe/FS® (Body Oil).

56. There are no other fluocinolone acetonide formulations or corticosteroid products that have demonstrated bioequivalence or therapeutic equivalence to Derma-Smoothe/FS® (Body Oil). Other products are not indicated for and contain specific warnings against using the products when 50% to 90% of the patients' bodies are involved. Consequently, no other fluocinolone acetonide formulation or other topical corticosteroid products can legally be interchanged with Derma-Smoothe/FS® (Body Oil). There is no generic for Derma-Smoothe/FS® (Body Oil).

57. Defendants have intentionally and with malice specifically stated that there are bioequivalent and/or therapeutic equivalents when presented with Derma-Smoothe/FS® (Body Oil) prescriptions to be filled by Defendant at various pharmacies across the country, including in the State of Florida. These statements concerning any bioequivalent and/or therapeutic equivalents of Derma-Smoothe/FS® (Body Oil) are false.

58. The Defendants intentionally and with malice have printed, published, and/or circulated, or caused to be printed, published, and/or circulated, statements and information, stating that there are bioequivalent and/or therapeutic equivalents when presented with Derma-Smoothe/FS® (Body Oil) prescriptions.

59. The unprivileged publication of such defamatory information to third parties has injured HDI, in that healthcare providers, patients, plan participants of the Defendants, and the general public have been provided false information as to the safety of Derma-Smoothe/FS® (Body Oil). As such, healthcare providers will avoid prescribing Derma-Smoothe/FS® (Body Oil). Moreover, patients also avoid purchasing and/or implementing Derma-Smoothe/FS® (Body Oil).

60. The unprivileged dissemination, communication and/or publication of such defamatory information has harmed and will continue to harm the reputation of HDI in the view of healthcare providers, plan participants of the Defendants, the general public, and the national pharmaceutical community. Further, such tortious actions by Defendants, as described above, will deter healthcare providers/prescribers, patients, plan participants of the Defendants, and/or general consumers from associating and/or doing business with HDI.

61. The unprivileged dissemination, communication and/or publication of such defamatory information by the Defendants have induced and continue to induce healthcare providers/prescribers, plan

participants of the Defendants, patients, and/or consumers to avoid prescribing and/or purchasing Derma-Smoothe/FS® (Body Oil).

62. As a direct and proximate result of the Defendants' unprivileged dissemination, communication and/or publication of the above-referenced defamatory information, HDI has suffered and continues to suffer compensatory and punitive damages, including, but not limited to, general, special, consequential, incidental, lost profits, lost revenue, diminution in value of the product, and diminution in value of HDI's reputation to the general consumer and the national pharmaceutical community.

COUNT IV

MISLEADING ADVERTISING

(FLORIDA STATUTES §817.41)

63. HDI realleges and incorporates by reference the allegations contained in paragraphs 1 through 32 of the Complaint as if fully set forth herein.

64. This is an action against the Defendants for violation of Florida Statutes, §817.41, prohibiting misleading advertising.

65. The Defendants are affirmatively suggesting the improper substitution of other drug products whenever a prescription is written for Derma-Smoothe/FS® (Body Oil).

66. The Defendants are affirmatively misrepresenting HDI's product to pharmacists as well as those receiving prescriptions by suggesting that other products are appropriate therapeutic substitutions for Derma-Smoothe/FS® (Body Oil), when they clearly are not.

67. HDI's product, Derma-Smoothe/FS® (Body Oil), and its predecessor compounds, has been proven, through well-documented published clinical studies dating back to the mid-1980's, to be safe and effective for patients with atopic dermatitis/eczema.

68. The Defendants have violated Florida Statues, §817.41, by publishing and/or disseminating false information concerning the safety of Derma-Smoothe/FS® (Body Oil) to the public in general, to the Defendants' plan participants located in the state of Florida, to the Defendants' plan participants located across the country, as well as to healthcare providers/prescribers both in Florida and nationally.

69. By virtue of the Defendants' affirmative misleading representations, patients and physicians are being forced to try other drugs that are unproven, potentially hazardous, and/or not effective in treating widespread atopic dermatitis/eczema on up to 50% to 90% of their body, merely because they are covered by the Defendants' medical plans.

70. The representations that the Defendants are disseminating in regards to Derma-Smoothe/FS® (Body Oil) prescriptions containing information which is known, or through the exercise of reasonable care and investigation could or might have been ascertained, to be untrue and misleading, and which is or was so made or disseminated with the intent or purpose, either directly or indirectly, of selling products or services and to induce the general public, healthcare providers/prescribers, as well as Defendants' Florida plan participants, to avoid the use of Derma-Smoothe/FS® (Body Oil), by making false, untrue, and/or misleading statements.

71. Such statements in the form of advertisements and/or representations, as identified above, constitute untrue and misleading statements. Specifically, Defendants knowingly misrepresented material facts concerning the safety and efficacy of Derma-Smoothe/FS® (Body Oil) by advertising on Derma-Smoothe/FS® (Body Oil) prescriptions that there are bioequivalent or therapeutic equivalents of Derma-Smoothe/FS® (Body Oil) available to patients and/or prescribers.

72. As a direct and proximate result of the Defendants' actions, as identified above, HDI has suffered and continues to suffer damages, including but not limited to general, special, consequential, incidental, lost profits, lost revenue, diminution in value of Derma-Smoothe/FS® (Body Oil), and devaluation of HDI's reputation with the general public, healthcare providers/prescribers, as well as the Florida and national pharmaceutical community.

COUNT V
DECEPTIVE AND UNFAIR TRADE PRACTICES
(FLORIDA STATUTES §501.201 et. seq.)

73. HDI realleges and incorporates by reference the allegations contained in paragraphs 1 through 32 of the Complaint as if fully set forth herein.

74. This action is brought against the Defendants pursuant to Florida's Deceptive and Unfair Trade Practices Act, Florida Statutes §501.201, et seq. HDI has standing to bring this action pursuant to Florida Statutes §§501.203(6) and 501.211(1).

75. The Defendants have communicated and disseminated and continue to communicate and disseminate false and misleading information. Specifically, Defendants knowingly misrepresented material facts concerning the safety and efficacy of Derma-Smoothe/FS® (Body Oil) by advertising on Derma-Smoothe/FS® (Body Oil) prescriptions that there are bioequivalent or therapeutic equivalents of Derma-Smoothe/FS® (Body Oil) available to patients and/or prescribers in Florida and elsewhere.

76. HDI's product, Derma-Smoothe/FS® (Body Oil), has been proven, through well-documented published clinical studies to be safe and effective. Derma-Smoothe/FS® (Body Oil) has no bioequivalent or therapeutic equivalent, and as such these drugs are required to be covered drugs in plans managed by the Defendants when the drugs are prescribed.

77. The Defendants knowingly misrepresented and misled healthcare providers/prescribers, the public in general, and the Defendants' Florida plan participants in particular, by disseminating, communicating, and/or publishing statements, representations, and/or information that was false and misleading. The Defendants have and continue to intentionally and willfully disseminate, communicate and/or publish this false and misleading information.

78. The Defendants induced and continue to induce Florida and national healthcare providers/prescribers, Florida plan participants, and the public in general to believe that there are bioequivalent and/or therapeutic equivalents available to Derma-Smoothe/FS® (Body Oil).

79. The Defendants' actions, as outlined above, offend public policy and are substantially injurious to HDI, as well as to the public in general and Florida plan participants in particular. To induce healthcare providers, Florida plan participants, and the public in general to forego and/or avoid the purchase and/or use of Derma-Smoothe/FS® (Body Oil) by disseminating false information throughout the state of Florida violates Florida Statute 501.201, et seq., among other statutes and common laws.

80. The Defendants' actions, as outlined above, have misled, continues to mislead, and is likely to mislead in the future, healthcare providers/prescribers, Florida plan participants, and/or the public in general as to the true safety and efficacy of Derma-Smoothe/FS® (Body Oil).

81. HDI has retained the undersigned law firm to prosecute this action and has agreed to pay attorney's fees and costs in order to pursue this claim. As a result, HDI is entitled to attorney's fees.

82. As a direct and proximate result of the Defendants' actions as outlined above, HDI has suffered and continues to suffer damages, including but not limited

to general, special, consequential, incidental, lost profits, lost revenue, attorney's fees, diminution in value of Derma-Smoothe/FS® (Body Oil), and devaluation of HDI's reputation with healthcare providers, the general public, and the national healthcare community.

WHEREFORE, the Plaintiff, HILL DERMACEUTICALS, INC., demands judgment for damages against Defendants in excess of Fifteen Thousand Dollars ($15,000.00), including costs, interest, and attorney's fees, and all such further relief as the Court deems just and appropriate.

Demand for Jury Trial

HDI hereby demands a trial by jury on all issues so triable against the Defendants.

s/ Neil P. Di Spirito

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UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTIRCT OF FLORIDA
ORLANDO DIVISION

HILL DERMACEUTICALS, INC. a Florida corporation,	)
Plaintiff,	)
v.	)**Case No. 6:07-cv-2032-GAP**
Rx SOLUTIONS, also known as PRESCRIPTION SOLUTIONS CORPORATION, a foreign corporation, UNITED HEALTHCARE COMPANY, PACIFIC HEALTH SYSTEMS, a foreign corporation, and UNITED HEALTHCARE OF FLORIDA, a Florida corporation,	)
Defendants.	)

PLAINTIFF'S, HILL DERMACEUTICALS, INC.'S, MOTION FOR REMAND, MEMORANDUM OF LAW, ALTERNATIVE REQUEST FOR JURISDICTIONAL DISCOVERY, AND 3.01(g) CERTIFICATION

The Plaintiff, HILL DERMACEUTICALS, INC. (herein "HDI"), by and through its undersigned counsel, hereby files its Motion for Remand and Combined

Memorandum pursuant to 28 U.S.C. § 1447, and M.D.L.R. 3.01(a). HDI is filing this Motion for Remand of the above-styled civil action from the United States District Court, back to the Circuit Court of the Eighteenth Judicial Circuit in and for Seminole County, Florida.

1. Introduction and Argument Summary

This is a simple case which Defendants wants to convolute. Defendant, United Healthcare of Florida, Inc. ("UHF"), a Florida corporation (Exhibit "A"). Therefore, there is no diversity as HDI is a Florida citizen.

HDI alleges UHF, and the other Defendants, are disseminating information and forcing the State of Florida pharmacists, *inter alia,* not regulated by the FDA, to illegally substitute for HDI's product when it is illegal to do so under Fla. Stat. § 465.025. HDI alleges in its Complaint that all Defendants, including UHF, are forcing and persuading pharmacists to substitute HDI's *Derma-Smoothe/FS® Topical Oil (Body Oil)* when it is prescribed by a physician for its indicated FDA approved use. (Compl. ¶ 22-32) Further, it is alleged that Defendants, including the State resident United Healthcare of Florida, are also falsely disseminating information about HDI's product. In essence, despite violating Florida statutory law, Defendants, including UHF, are telling pharmacists, requiring alleged substitutions, or not covering payment on HDI's product when prescribed, and instead requiring substitution of some other product, usually more expensive, when by law that other product is not a generic for *Derma-Smoothe/FS® Topical Oil (Body Oil)* (which has no generic), nor a bioequivalent drug for the indicated (or approved for) disease of atopic dermatitis/eczema, as otherwise more specifically alleged in the operative Complaint.

Defendants make several misleading arguments for removal. They characterize atopic dermatitis/eczema as a

"skin irritation". They want this Court to think we are dealing with some minor skin rash. However, atopic dermatitis/eczema is a chronic disease afflicting 20% to 25% of the world's population. (American Academy of Allergy, Asthma and Immunology, www.cmeweb/derm/aciaairept.htn). It can be a debilitating disease with adverse social consequences, particularly in children. (*See University of Kentucky College of Medicine, American Academy of Allergy, Asthmas and Immunology, supra*). Exhibit "B" is an example of this little "skin irritation". See www.skincarephysicians.com/eczemanet/whatis.html.

Second, there is no federal question raised. Just because the FDA is mentioned in HDI's Complaint does not raise a federal issue. Defendants argue about labeling and approval, but there are no issues like that framed by the Complaint. The alleged substitution is controlled by State law, and the false dissemination of information about HDI's product is grounded in State claims for relief.

Defendants argue in removal hiding behind a corporate shell game that UHF is not involved. However, upon information and belief, UHF contracts with Rx or Prescription Solutions for Florida residents. They are the agent for UHF. They get paid by UHF, and benefit by substitution of drugs. Most importantly, UHF is the payor. UHF is where the money comes from. This possible "hiding the ball" seems to be recognized by Defendants for in their Removal papers they say of UHF about decision making on substitution, it "does not ordinarily make formulary decisions." (¶ 18)(Dkt. 1) Well, they either do or they don't. Accordingly, HDI asks this Court, as part of the Motion to Remand, to allow discovery on these matters if there is any real jurisdictional issue—although HDI does not believe so. But if the Court does, let's look at the Contract with UHF and PBM, and take 30(b)(6) jurisdictional depositions. As it appears now,

when the PBM or Rx/Prescription Solutions' shell is lifted, the "nut" ultimately underneath ends up with United Healthcare Group, which includes UHF (Exhibit "C").

A generically equivalent drug means a product which has the same active ingredients, finished dosage form, and strength. Any such substitution is countenanced by State law. Section 465.025 defines generically equivalent product as one which is an A or an AB product, as reference listed in the FDA Orange Book. The FDA Orange Book is not statutory or regulatory law. It is only a reference tool. One cannot bring a private cause of action based on the Orange Book. Thus, the entire basis of authority of Defendant's wrongful conduct is grounded on illegal substitution by pharmacists under State legislation, not any jurisdictional required federal question for this Court's jurisdiction.

In essence, the State of Florida regulates substitution of prescribed drugs by pharmacists. The State of Florida makes it clear in the aforementioned Fla. Stat. 465.025 that it adopts as a reference only to therapeutic equivalent compounds as listed in the FDA Orange Book. Hence, there is no question about interpretation of therapeutic equivalence. Instead, the interpretation is one of Florida State law of generic substitution regulation.

The Plaintiff or Defendants in their Motion for Removal have not questioned the scientific or regulatory authority of the United States Food and Drug Administration. Instead, Plaintiff is merely making the claim that it is illegal for Florida pharmacists who are being forced to substitute a non-therapeutically equivalent drug by Defendants. Also, that physicians cannot be told by Rx or Prescription Solutions, or for that matter any of the United Healthcare companies, including United Healthcare of Florida, they must use any general steroid

substitute which is not therapeutically equivalent to HDI's products, or even indicated for the particular disease treatment the physician prescribed the medication for. Further, HDI's products have no generic equivalent or bioequivalent substitute for its approved parameters of atopic dermatitis or eczema treatment. The regulation of pharmacy and how it is practiced is clearly under the control of the laws of the State of Florida.

All Florida operations of the United Healthcare companies, a United Health Group Company, are conducted by and through United Healthcare of Florida. All decisions made about patients, payor benefits, UHF's Medicare Preferred Drug List, and all other decisions and operations for the State of Florida are made by the United Healthcare Company of Florida. Rx or Prescription Solutions, a United Health Group company, administers or supplies pharmacy benefit management (PBM) advice and administration to United Healthcare of Florida. As payor, however, United Healthcare of Florida decides which medications to cover and retains legal responsibility. Therefore, no improper or fraudulent joinder can be asserted. ("Some PBMs are part of larger managed care organizations such as Prescription Solutions [which is a subsidiary of United Health Group]." (See Exhibit "D"), (emphasis added).

2. The Facts

1. On or about November 16, 2007, Plaintiff HDI filed its Complaint in the Circuit Court of the Eighteenth Judicial Circuit in and for Seminole County, Florida (Case No. 2007CA003772, Exhibit 2 to Notice of Removal, Docket No. 1).

2. On or about November 27th, 2007, the Defendants received, through service of Summons and Complaint on their Registered Agents in Florida, a copy of the initial pleadings set forth for the claim of relief upon

which this action is based. True and correct copies of the Summons and the original Complaint served on the Defendant were served with the Notice of Removal (Exhibits 1-2, Docket No. 1). Also, served with the Complaint in the State Court were the Requests for Discovery, including Interrogatories, Requests for Admissions and Requests for Production, First and Second (Notice of Removal, Exhibits 3-10, Docket No. 1)

3. HDI's claims do not present any federal question jurisdiction as they are not grounded on any private action under federal law, or an interpretation of a federal question of law. The core allegations of HDI's Complaint lie in State, and not federal law. HDI's claims are further based on Equity Relief, Florida statutory and common law and Defendant's violation of the Florida Deceptive and Unfair Trade Practices Act.

4. References to the FDA Orange Book appear and are relevant only as a reference material and not statutory in nature. The FDA Orange Book in and of itself has no statutory effect.

5. HDI distributes and markets *Derma-Smoothe/FS® Topical Oil (Body Oil)* for all fifty (50) states, including specifically Florida. This prescription drug is the only corticosteroid which has proven safe and effective by the Food and Drug Administration for atopic dermatitis/eczema in pediatric patients 3 months and older[1] with up to 50% to 90% body involvement. However, HDI's tort claims and relief are based on Florida Statutes § 465.025(b), which states a "generically equivalent product means a drug product with the same active ingredient finished dosage form and strength". Violation of the State statute created the damage to HDI.

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[1] FDA has recently changed indication from 2 years and older to 3 months and older because of its exceptional safety profile.

6. *Derma-Smoothe/FS® Topical Oil (Body Oil)* is the only low potency topical corticosteroid that has been granted a full new drug approval by the FDA for the specific indication of atopic dermatitis/eczema in patients 3 months and older with treatment of up to 50% to 90% of the body without adrenal suppression. As such, *Derma-Smoothe/FS® Topical Oil (Body Oil)* has no bioequivalent or therapeutically equivalent generic drug. *Derma-Smoothe/FS® Topical Oil (Body Oil)* is the FDA's referenced listed drug as set forth in the agency's Orange Book.[2] Therefore, no generic substitute exists under Florida Statutes § 465.025. Since Florida Administrative Law governing licensed pharmacy practice governs generic substitutions, anything to do with dispensing or substitution of prescription drugs is exclusively a State issue. The FDA does not regulate pharmacists.

7. In order to obtain a new approval from the FDA for *Derma-Smoothe/FS® Topical Oil (Body Oil)*, HDI incurred great time and expense to complete the requisite FDA safety and efficacy studies. As there is no bioequivalent or generic equivalent product approved by the FDA for *Derma-Smoothe/FS® Topical Oil (Body Oil)* managed care organizations are required to cover *Derma-Smoothe/FS® Topical Oil (Body Oil)* if they treat and/or cover atopic dermatitis/eczema in patients 3 months and older with 50% to 90% body involvement to minimize adrenal suppression. Rx or Prescription Solutions and United Healthcare of Florida, a United Healthcare company and a United Health Group company, have disseminated and continue to disseminate false, deceptive, misleading and fraudulent information to Florida health care providers and United Healthcare of Florida Plan participants, and to others throughout the United States,

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[2] See listing in Orange Book – http:\\www.accessdatafda.gov\scripts\cder\ob\docs\tempi.cfm

regarding the Plaintiff's product, *Derma-Smoothe/FS® Topical Oil (Body Oil)*. Specifically, *Derma-Smoothe/FS® Topical Oil (Body Oil)* prescriptions by licensed physicians in the State of Florida are expected to be filled and reimbursed by the Defendants and/or its retail or mail order pharmacies, without restriction to the physicians' prescribing. Restricting a physician for prescribing the only indicated drug for atopic dermatitis/eczema for patients 3 months or older with 50% to 90% body involvement with clinical proof of no adrenal suppression is clearly illegal under Florida Statute § 465.025.

8. Informing physicians, as HDI alleges these Defendants are doing and continue to do, that the only indicated drug for atopic dermatitis/eczema, in patients 3 months and older with 50% to 90% body involvement that prevents adrenal suppression, that this product cannot be used first line because it will not be paid for until other non-indicated drugs in that category fail, is clearly tantamount to coercing physicians to prescribe off-label.

9. While physicians are free in their professional judgment as the learned intermediary to prescribe off-label if they so choose, it is well established law that the prescribing of a doctor for a patient with the only indicated drug for a diagnosed medical condition cannot be interfered with by third party sources. HDI demanded that Defendants, including the resident Florida corporation, to cease and desist from preventing doctors from prescribing the only indicated product for atopic dermatitis/eczema in patients 3 months and older with 50% to 90% body involvement to avoid adrenal suppression as first line treatment. In light of this false information, patients will use less safe and efficacious products and products not indicated for their diagnosed medical condition.

10. HDI demanded that Defendants cease and desist their practices but they, including the Florida

corporate Defendant here, failed and refused to do so. Thereafter, HDI filed suit in the Seminole County Circuit Court and served all Defendants via their registered Florida agents within the appropriate period of time.

3. Standard of Review

11. "Where there is any doubt concerning jurisdiction of federal court on removal, the case should be remanded." *Martin, R.N. v. Mentor Corp.*, 142 F.Supp.2d 1346 (M.D. Fla. 2001) citing *Campos v. Sociedad Aeronautica de Medallin Consolidada, S.A.*, 882 F.Supp. 1056, 1057 (S.D. Fla. 1994). Doubts as to whether removal of an action is permissible should be resolved against removal. *Mentor Corp.*, 142 F.supp.2d at 1347 citing *Roe v. O'Donohoe*, 38 F.3d 298, 303 (7th Cir. 1994). If a case is removed improvidently or without necessary jurisdiction, it must be remanded. *Mentor Corp.*, 142 F.Supp.2d at 1347 citing *Campos*, 882 F.Supp. at 1057.

12. In determining whether either exists, the Court must analyze the allegations contained in the complaint at the time of the removal. *Id. See also, Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 805 (1986); *Woods v. Firestone Tire & Rubber Co.*, 560 F.Supp. 588, 590 (S.D. Fla. 1983); *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 ("The fact that a defendant might ultimately prove that a plaintiff's claims are preempted does not establish that they are removable to federal court.")

4. The Removal Documents

13. The Defendants filed their Notice of Removal on December 27, 2007 (Docket No. 1). The instant case was removed without the necessary jurisdiction and it should be remanded accordingly. "Where there is any doubt concerning jurisdiction to federal court on removal, the case should be remanded." *Martin R. N. v. Mentor Corp.*, 142 F.Supp.2d 1346 (M.D. Fla. 2001), citing *Campos v. Sociedad Aeronautica v. Medallin Consolidada, S.A.*, 882

F.Supp.2d 1056, 1057 (S.D. Fla. 1994). Doubts as to whether the removal of an action is permissible must be resolved against the removal. *Mentor Corp.*, 142 F.Supp.2d at 1347, citing *Roe v. O'Donohoe*, 38 F.3d 298 303 (11th Cir. 1994). If a case is removed improvidently or without necessary jurisdiction, it has to be returned to the State Court by remand. *Mentor Corp.*, 142 F.Supp.2d at 1347, citing Campos, 882 F.Supp.2d at 1057.

14. Federal jurisdiction can be based upon either: a) a federal question; or b) diversity of citizenship and an amount in controversy exceeding $75,000. *Cacciatore v. Liberty Life Assurance Co. of Boston*, 85 F.Supp.2d 1282, 1284 (M.D. Fla. 2000). See 28 U.S.C. § 1331, 28 U.S.C. § 1332. In determining whether jurisdiction exists, the Court must analyze the allegations contained in the Complaint at the time of the removal. *Merrill Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 805 (1986) (The fact that a defendant might ultimately prove that a plaintiff's claims are pre-empted under federal law does not establish their removal to federal court.) In the Notice of Removal, Defendants state that: "Plaintiff's claims require the Court's interpretation of labeling ruling and regulations governed by the Food, Drug and Cosmetics Act. F.D.C.A. [See 21 U.S.C. § 331 2007], and regulations governing the formulary of the alleged prescription drug providers pursuant to Part D of the Medicare Modernization Act ("MMA")." This is entirely untrue and false. The resultant damages are violations of State law and no federal interpretation of any law is required nor is any claim based upon federal statute or regulations. The State of Florida has decided in House Bill 69, signed into public law in 2001-146, that the FDA Orange Book would be used as a reference guide in determining generic substitution. The Orange Book only identifies therapeutically and bioequivalent drugs which can be substituted by A or AB, for the referenced drug or not.

The FDA Orange Book is completely used as a reference and not a statutory authority.

15. Defendants misrepresent the disease entity and the law when they state: "Plaintiff is wrong that its medicine is the only appropriate FDA-approved treatment for skin irritations." The disease entities we are talking about here may manifest with skin irritations, but are not mere skin irritations. Atopic dermatitis or eczema is a hyper-sensitive reaction of the skin to allergens called "haptens". The skin reaction is manifested as eczematous. The resulting manifestations of atopic dermatitis/eczema include a wide array of symptoms from redness, scaling, lichenification, eczematous dermatitis (also referred to as atopic dermatitis) are allergic responses. The prevailing clinical thought in evidence is that eczema/atopic dermatitis is considered a genetic disease. Therefore, atopic dermatitis/eczema is a hereditary conditioned allergenic response, within an individual's DNA. An array of well known medical authorities, treatises, textbooks, and the Center for Disease Control all concur that atopic dermatitis/eczema is an allergenic response to haptens. This is a far cry from the "skin irritations" that the Defendants' claim many drugs are indicated for. No other drugs indicated for skin irritations address the underlying causes of a hapten allergenic response as occurs in atopic dermatitis/eczema. Therefore, *Derma-Smoothe/FS® Topical Oil (Body Oil)* is the only approved treatment for atopic dermatitis/eczema in patients 3 months or older with 50% to 90% body involvement. Further to that point, clinical studies accepted by the FDA clearly prove that *Derma-Smoothe/FS® Topical Oil (Body Oil)* is the only treatment that can be used safely in patients with 50% to 90% body involvement without danger of adrenal suppression.

16. This Court is not being asked to interpret the disease entity states as established by the medical

community or its appropriate treatment. This Court is only being asked to interpret the State law concerning the illegal substitution of a non-A or AB drug for the referenced pharmaceutical.

5. Subject Matter Jurisdiction – Federal Question

17. As courts of limited jurisdiction, federal courts may only adjudicate cases that the Constitution and Congress have granted them authority to hear. *Meinders v. Refco Securities, Inc.*, 865 F.Supp. 721, 723 (D.Colo. 1994); *Todd Holding Co., Inc. v. Super Valu Stores, Inc.*, 744 F.Supp. 1025, 1026 (D.Colo. 1990). For subject matter jurisdiction to exist under § 1331, the civil action must "arise under" the Constitution, laws or treaties of the United States. *Meinders*, 865 F.Supp. at 723; *Aetna Ins. Co. v. Chicago, R.L.. & P.R. Co.*, 229 F.2d 584, 586 (10th Cir. 1956). The burden of establishing federal jurisdiction based upon a federal question rests firmly on the party seeking removal of the action to the district court. *Meinders*, 865 F.Supp. at 723; *Bromenn Healthcare v. Northwestern Nat. Life Ins. Co.*, 806 F.Supp. 799, 803 (C.D.Ill. 1992). Thus, in order to justify removal, Defendants must establish federal jurisdiction overcome the strict construction of the jurisdictional statute. *Meinders*, 865 F.Supp. at 723. Defendants cannot meet this burden.

18. The presence of federal question jurisdiction is governed by the "well pleaded complaint" rule. *Jackson v. The Purdu Pharma Co.*, 2003 W.L. 21356783, *5 (M.D. Fla. April 11, 2003); *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 808 (1986). Under this rule, a case "arises under" federal law making it removable, only if a federal claim exists on the face of plaintiff's complaint. Id.

19. In so moving, the issue is whether this Court has subject matter jurisdiction over removed claims.

Mansfield, C. & L. M. R. Co. v. Swan, 111 U.S. 379, 382 (1884). Despite the Plaintiff's exclusive reliance on State law in its Complaint, the Defendants nevertheless claim that removal is proper under 28 U.S.C. § 1441 because the Plaintiff's claims "arise under" the laws of the United States within the meaning of 28 U.S.C. § 1331. The Defendants' arguments run contrary to settled law governing the subject matter jurisdiction of the federal courts. The Plaintiff's Complaint does not affirmatively rely or raise any issue of federal law, and this action is therefore not within the federal subject matter jurisdiction of this Court. Thus, the question whether this action was properly removed turns upon whether the Plaintiff's Complaint could have been brought originally in federal court. *Caterpillar, Inc. v. Williams,* 482 U.S. 386, 392 (1987) (Only State court actions that originally could have been filed in federal court may be removed to federal court by the Defendant.)

20. The burden of establishing federal-subject matter jurisdiction is, of course, on the parties seeking removal. The Federal Rules of Civil Procedure provide that whenever it appears by suggestion of the parties or otherwise that the Court lacks jurisdiction of the subject matter, the Court shall dismiss the action. Fed. R. Civ. P. 12(h)(3). The claims brought before this Court, pursuant to removal, dictate that the proper course of action is to remand the claims if such subject matter jurisdiction is lacking.

21. It is long settled that the mere presence of a federal issue in a State cause of action does not confer federal question jurisdiction. It does not automatically render the cause of action the kind of adjudication for which "jurisdiction would serve congressional purposes in the federal system". *Community State Bank Cash America Financial Services, Inc. v. James Strong,* 485 F. 3d 597 at

620 (11th Cir. 2007), *citing Merrill Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 813-14 (1986).

22. For a claim to arise under federal law, the result of the suit must depend on the determination of a dispute or controversy respecting the validity, construction or effect of federal law. *Shulthis v. McDougal*, 225 U.S. 561, 569. A federal question exists only when the complaint establishes either that federal law creates the cause of action, or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law. A mere reference to a federal program such as the Medicare Modernization Act, Part D, Prescription Pharmaceuticals of 2003, as amended in 2006 in the Complaint does not make the MMA citation an essential element of the Plaintiff's claim. *Community State Bank Cash America Financial Services, Inc. v. Strong*, 485 F. 3d at 597, *citing Albert Einstein Medical Center v. National Benefit Fund for Hospital and Healthcare Employees*, 740 F.Supp. 343, 348 (E.D. Pa. 1989).

23. Because the Plaintiff is master of his claim, he may avoid federal jurisdiction by laboring to rely exclusively on Florida State law. *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 392 (1987). As previously stated, the Court must determine matters of federal jurisdiction by reference to the well pleaded complaint rule by which federal courts have jurisdiction to hear only those cases in which a well pleaded complaint establishes that the federal law creates the cause of action. Under the well pleaded complaint rule, federal courts do not have jurisdiction over State claims simply because the defendant may or does assert a federal defense. *Caterpillar, Inc. v. Williams*, 482 U.S. at 393. Federal pre-emption is merely a defense to the allegation in the Plaintiff's Complaint. *Id.* at 392. Therefore, pre-emption of State law claims as a rule does not justify removing those claims to federal court. *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58 (The

Supreme Court announces that it is now settled law that a case may not be removed to federal court on the basis of a federal defense.) The core allegations of HDI's Complaint are made under State law.

24. The Defendants' insinuations that HDI's claims hinge on FDA statutes and regulations are incorrect. Indeed, the FDA statutes and regulations do not provide for a private cause of action for drug companies under the MMA. There is no private cause of action under the FDCA. HDI is not able to bring any claim under the MMA currently nor is it attempting to do so. *Harris v. McDonald's Corp.*, 901 F.Supp. 1552 (M.D. Fla. 1995). In *Harris,* the Court stated the absence of private action under the statute, the FDCA, upon which the plaintiff's claim relied obviated the federal question upon which this jurisdiction depends. The FDA regulations and FDCA rules are not available as a basis for federal question jurisdiction in this matter. *Stephens v. Danick Medical, Inc.*, 1999 Westlaw 33217282 (S.D. Fla. 1999); *State of Florida v. Eli Lilly Co.*, 329 F.Supp. 364 (S.D. Fla. 1971).

25. While it is true that HDI's Complaint does refer to the MMA and the FDA, the Complaint does not refer to the FDA's pre-emptive jurisdiction. Defendants have misrepresented these comments erroneously claiming that the FDCA, through the FDA statutes and regulations, underlie HDI's claims. In actuality, the converse is true. Plaintiff's cite 21 U.S.C. § 331 (2007), and the regulations governing the formulary and prescription drug providers pursuant to Part D of the Medicaid Modernization Act. Nowhere in that Section does it determine that the regulation of pharmacy, and of generic substitution by pharmacists are in any way governed by the federal government. Also, nowhere in that section does it determine that the regulation of medical doctors and the regulation of the practice of medicine by doctors are in any way governed by the federal government.

26. The United States District Court, Middle District of Florida, Orlando Division, denied a similar removal attempt in the *Jackson* case. *Jackson v. Purdue Pharma,* 203 U.S.Dist. Lexis 6998 (2003). In *Jackson,* the plaintiff filed a class action suit in State court against the manufacturers and distributors of the drug, Oxycontin, stating claims for violations of the Florida Deceptive and Unfair Trade Practices Act and Medical Monitoring Act. *Id.* at *1. Defendants then removed the action to the Middle District Court alleging jurisdiction under diversity of citizenship, as well as federal question, and plaintiff moved for remand. *Id.* at *16. In looking at the federal jurisdiction question this Court determined that a case "arises under" federal law only if a federal claim exists on the face of the plaintiff's complaint. *Id.* at *16. The defendants in *Jackson* argued that plaintiff's claims were a substantial issue of federal law because they asked the State court for injunctive relief which would displace the congressionally mandated role of the FDA regulating the approval, marketing, manufacturing and distribution of Oxycontin. Id. at *17. This Court again looked to the holding in *Merrill Dow Pharmaceuticals, Inc. v. Thompson,* where the plaintiff had brought suit in State court against the manufacturer of the drug Benedectin alleging that the manufacturers' violation of the Food, Drug and Cosmetics Act (FDCA) constituted negligence. *Id.* at *19. This Court noted there was no federal cause of action for violations of the FDCA, and emphasized the importance of that factor, and what it characterized as the well settled framework for evaluating whether a federal cause of action lies. *Id.* at *19 citing *Merrill Dow Pharmaceuticals, Inc. v. Thompson,* 478 U.S. 811. Thus, it is now settled that a case cannot be removed to federal court on the basis of a federal defense, including the defense of pre-emption, even if it is anticipated from the plaintiff's complaint, or even if both parties concede that a federal defense is the only question

truly at issue. First established, it is a matter of well settled law since the time of *Louisville and Northern Railroad Co. v. Mottley,* 219 U.S. 467 (1911). For a more modern citation making the same contention, *see Caterpillar, Inc.,* 482 U.S. at 393.

27. Defendants argue that federal regulations dictate the formulary requirements for the Part D provider. Again, Defendants are misleading or misrepresenting their arguments. Chapter 6 of the Medicare, Part D Drugs and Formulary Requirements, states that Part D formularies must include drug categories in classes that cover all disease states. Providing a drug without indication for a particular disease clearly violates that statement. Medicare Part D Manual, Chapter 6, 30.2.1, Formulary and Classes. However, again, this is not the point of the argument or the claims for relief in question. Instead, HDI is maintaining that under Florida law pharmacists (who are not regulated by the FDA) may not dispense a non-therapeutically equivalent drug as a generic. It is evident that the indicated disease state, according to Florida law, is not being covered with the indicated prescription. Again, the federal regulations and documents cited aforementioned clearly exclude the federal government, FDA, Centers for Medicare and Medicaid Services, from any regulation of the practice of pharmacy or medicine. What Defendants are stating is that if a therapeutically equivalent drug is approved by the FDA, listed in the Orange Book, and this is a different brand than the brand indicated for the same exact indication that exists on the formulary, then a patient has the right to lodge an appeal under the MMA. Accordingly, 42 C.F.R. § 423.566 and § 423.578 cited by the other side have absolutely no applicability here.

28. In accordance with the *Morales* case, it appears that analysis of the complaint would result in a determination that subject matter jurisdiction is lacking

for the federal court, inasmuch as Plaintiff limited his complaint to causes of action based exclusively on State law. *Morales v. Showell Farms, Inc.,* 910 F.Supp. 244 (M.D. N.C. 1995). In conclusion, there is no arguable point that the Plaintiff has raised any federal question which needs to be solved in their Complaint. There can be no federal question jurisdiction.

6. Removal Pursuant to 28 U.S.C. § 1332 Diversity of Citizenship

29. This Motion for Remand is also based upon the fact that Defendants have not established a basis for federal court jurisdiction pursuant to 28 U.S.C. § 1332, et. seq.

30. The Defendants attach their hopes of removal of this action on requesting this Court to pre-judge the merits of this case. *Tedder v. F.M.C. Corp.,* 590 F. 2d 115, 117 (5th Cir. 1979). *See also, Graham v. Medtronics,* 2006 U.S. Dist. Lexis 72394 *5. This would be improper, and of course Defendants have no support for their now trying to create a new standard by which this Court examines remunerable actions. *Id.* There is a non-diverse Florida plaintiff, and at least one non-diverse Florida defendant to this action. Specifically, Hill Dermaceuticals, Inc. is a Florida corporation. United Healthcare of Florida is a Florida corporation. (See Exhibit "A"). Thus, the only way Defendants can try to seek removal is if they can establish fraudulent joinder. However, the standard for establishing fraudulent joinder is an extremely high standard, a burden as the Courts have placed on a removing defendant. *Batoff v. State Farm Ins. Co.,* 977 F. 2d 848, 851 (3rd Cir. 1992).

31. It is undisputed that HDI is a Florida corporation chartered under Florida law with its principal place of business and head offices in Sanford, Florida. It is also undisputed that United Healthcare of Florida is a

licensed Florida insurer and incorporated under the laws of the State of Florida with its principal place of business and business activities solely in the State of Florida. (Exhibit "A").

32. United Healthcare of Florida would have to surmount a very high hurdle. There are bases for independent causes of action under Florida law against United Healthcare of Florida, the non-diverse Defendant. It is not a question for removal whether or not the Plaintiff can ultimately prove their case, which they believe they can. Instead, it is whether or not any type of cause of action has been alleged for which they can prevail. The Defendant must show there is no possibility of prevailing under Florida law which the Defendant cannot. *See Betts v. Eli Lilly & Co.,* 435 F.Supp.2d 1180 (S.D. Al. 2006), *citing Cordle v. Mercer & Co.,* 405 F.supp.2d 800, 803 (E.D. N.Y. 2005). (To prove fraudulent joinder, the party must present sufficient evidence that a plaintiff could not have established a cause of action against non-diverse defendants under State law.) Accordingly, this Court must remand this case to the Eighteenth Judicial Circuit Court for the State of Florida located in Seminole County, Florida.

33. United Healthcare of Florida was joined because it is the licensed insurer of the United Health Group companies and fully integrated in using the pharmacy benefit management services of Rx or Prescription Solutions. As the licensed Florida insurer, all operations in the State of Florida for United Health Group or United Healthcare Company are conducted through United Healthcare of Florida. Defendants say UHF is not involved in anything, but the operative Complaint alleges they are. This is a matter of proof, not jurisdiction. As such, on this Record, as required for fraudulent joinder, UHF cannot establish there is no possibility, by clear and convincing evidence, that HDI cannot establish a cause of

action against UHF. *Clincy v. Oce North America Inc.*, No. 6:07cv226ORL28DAB, 2007 WL 1427492, at *2 (M.D. Fla. May 14, 2007).

34. Defendants go on to assert that United Healthcare of Florida does not maintain the formulary or prescription drug list and does not ordinarily make formulary decisions. Yet, from their website (www.uhc.com) and the materials supplied, United Healthcare of Florida in its Section 5F, Prescription Drug Benefits clearly states they use a preferred prescription drug list (PDL). "Our PDL Management Committee creates a list that identifies FDA approved prescription medications, products or devices that are planned as preferred for use." *Id.* It goes on to state that Tier 1, Tier 2 and Tier 3 exists with co-payment options. They claim that United Healthcare of Florida's PDL's Management Committee makes the final tier classifications by considering a number of factors, including but not limited to, clinical and economic factors. *Id.*

35. While true that United Healthcare of Florida does contract with pharmacy benefit managers to coordinate and administer its pharmacy benefit provisions ("PBMs"), it is also an undisputable fact that United Healthcare of Florida maintains its own pharmacy and therapeutic committee which makes the ultimate decisions on which drugs, like HDI's products they are seeking to substitute will be included. (www.uhc.com, Section 5F.)

36. Defendants' removal claim is devoid of any reference to communications between United Healthcare of Florida and any other medical health professional, pharmacists, or member insured, about *Derma-Smoothe/FS® Topical Oil (Body Oil).* Defendants themselves state they contract Rx or PBMs to handle the correspondence at United Healthcare's direction. Defendants cannot have a PBM used as both sword and

shield. United Healthcare directs Rx and other PBMs it contracts with to say "no" to patients on United Healthcare's behalf. The correspondence itself states, *your Plan payor does not include Derma-Smoothe/FS® Topical Oil (Body Oil) on its preferred drug list.* There is clear reference in the correspondence that Rx is an administrative and pharmacy benefit manager, and that as the payor, United Healthcare of Florida makes the reimbursement decisions, and the substitution issue. If it does not pay, then the pharmacist must substitute because of the payor, United Healthcare of Florida.

37. The Defendants have not presented a viable argument here that there is no possibility of success that United Healthcare of Florida involved here has no independent liability. As noted, under Florida law there is substantive liability against these non-diverse Defendants. The "no possibility" of success language used by the Courts, or no possibility of prevailing, are strong words indeed. This is akin to a Summary Judgment standard. These Defendants cannot in any way clear that hurdle or surpass it upon the well pleaded allegations or Plaintiff's supporting evidence. The fact that United Healthcare of Florida and Rx or Prescription Solutions have produced misleading information to doctors and pharmacists throughout the State of Florida, and the nation, has created the detrimental situation where doctors and pharmacists are being coerced into using or substituting an improper pharmaceutical for the only indicted pharmaceutical to prevent adrenal suppression in patients with atopic dermatitis/eczema in patients with 50% to 90% body involvement.

38. The burden is on the Defendants "to show fraudulent joinder, and, as with any dispute over removal, all doubts are to be resolved against removal." *Cordle v. Merck & Co., Inc.*, 435 F.Supp.2d 800, 803. "To prove fraudulent joinder, the removing party must present

sufficient evidence that a plaintiff could not have established a cause of action against a non-diverse defendant under State law." *Id.*

39. By virtue of the fact stated in the above paragraphs, it is clearly demonstrated that Plaintiff and Defendant are citizens of the State of Florida for the purpose of diversity jurisdiction.

7. Relief Requested

By the virtue of the stated facts above, and in all previous paragraphs it is clear that Defendants have not established: (1) a federal question for jurisdictional purposes; or (2) a diversity of citizenship for federal jurisdiction; and (3) HDI seeks attorneys' fees for this improvidently removed case. 28 U.S.C.A. § 1447(e). Therefore, this case must be remanded.

In the alternative, if this Record is not complete, HDI then requests the Court to conduct discovery on the diversity and federal question jurisdiction. For example, on the diversity issue, obtaining the contract between United Healthcare of Florida and the PBM, and taking Rule 30(b)(6) depositions of both entities to establish, ultimately, contractually the PBM is just a conduit for the healthcare company, its agent, and the money for the payment of the substituted drugs and commissions to the PBM comes from UHF.

3.01(g) CERTIFICATION FOR HILL DERMACEUTICAL'S MOTION FOR REMAND AND MEMORANDUM OF LAW IN SUPPORT OF MOTION

I HEREBY CERTIFY that Neil Di Spirito, Esquire, for Plaintiff, HILL DERMACEUTICALS, INC., and Edmund Loos, Esquire, and Noam Fischman, Esquire, for Defendants, Rx or PRESCRIPTION SOLUTIONS CORPORATION and UNITED HEALTHCARE OF FLORIDA, have had teleconferences and conferences on the Remand Motion to meet the provisions of Local Rule

3.01(g) and counsel could not agree on the resolution of the Motion.

WHEREFORE, Plaintiff hereby respectfully moves for remand of the above-captioned action pending in the United States Federal Court for the Middle District of Florida, Orlando Division.

/s/ Larry M. Roth
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Neil P. Di Spirito, Esquire
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Hill Dermaceuticals, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 29th, 2008, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF System which will send a Notice of Electronic Filing to: Edmund O. Loos III, Esquire and Amanda L. Chapman, Esquire, GREENSPOON MARDER, P.A., Capital Plaza I, Suite 500, 201 East Pine Street, Orlando, FL 32801 and by electronic mail to William A. Davis, Esquire, MINTZ,
LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C., 701 Pennsylvania Avenue, NW, Washington, DC 20004-2608 (wadavis@mintz.com).

/s/ Larry M. Roth
Larry M. Roth, Esquire
Florida Bar No. 208116

9

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

HILL DERMACEUTICALS, INC. a Florida corporation,	)
Plaintiff,	)
v.	)**Case No. 6:07-cv-2032-GAP**
Rx SOLUTIONS, also known as PRESCRIPTION SOLUTIONS CORPORATION, a foreign corporation, UNITED HEALTH GROUP, INC., a foreign corporation, and UNITED HEALTHCARE OF FLORIDA, INC., a Florida corporation	)
Defendants.	)

AMENDED COMPLAINT

General Jurisdiction, Venue and Parties

I. Introduction

Plaintiff, HILL DERMACEUTICALS, INC. ("HDI"), by and through its undersigned counsel, hereby sues the Defendants, Rx SOLUTIONS, also known as PRESCRIPTION SOLUTIONS CORPORATION, a foreign corporation doing business in Florida; the UNITED

HEALTH GROUP, INC. of Minnetonka, Minnesota, parent organization of Rx or PRESCRIPTION SOLUTIONS; and UNITED HEALTHCARE OF FLORIDA, INC., a Florida corporation, citizen, and Florida licensed health insurer ("Defendants"). HDI alleges the following:

This is an action for damages that exceeds $75,000, exclusive of interest, costs, and attorneys' fees.

II. Parties

1. Plaintiff, HDI, is a Florida corporation and citizen of the State, incorporated under the laws of the State of Florida with its principal place of business located at 2650 South Mellonville Avenue, Sanford, Seminole County, Florida 32773-9311. HDI is the developer and manufacturer of *Derma-Smoothe/FS® (Body Oil),* and is the owner of the NDA for this drug.

2. Defendant, Rx or Prescription Solutions, is a pharmacy benefit manager, and a wholly owned subsidiary of the United Health Group, Inc. of Minnetonka, Minnesota. Rx or Prescription Solutions does extensive business in Florida. Rx or Prescription Solutions provide pharmacy benefit management services to its sister company, United Healthcare of Florida, Inc. (Also, a United Health Group, Inc. company).

3. United Healthcare of Florida, Inc. ("UHF"), a Florida citizen and resident Defendant, is a Florida licensed health insurer. UHF is also a wholly owned subsidiary and an integrated company of the United Health Group, Inc. ("UHG"). Any business undertaken in Florida by United Health Group, Inc. of Minnetonka, Minnesota is handled through UHF. UHF is a Florida corporation with its principal place of business in Maitland, Florida. All decisions and operations involving patient lives, prescription coverage and operations in the State of Florida are made by UHF as UHG's operating arm.

4. UHF, the Florida defendant citizen, is also the payor and the organization with the ultimate responsibility for the pharmacy benefit management decisions that are made for patients in UHF's health plans. UHF's plans include employees of the State of Florida, and United Medicare Rx, a Medicare prescription drug plan ("PDP"), which is operated and managed in Florida by UHF.

5. UHF exclusively conducts the business of UHG, its parent organization in the State of Florida.

6. Rx or Prescription Solutions provides pharmacy benefit management services to patients of UHF.

7. Under the UHG companies, UHF and Rx or Prescription Solutions reimburse, manage, and operate health plans within the State of Florida.

8. UHG, through its integrated companies such as Rx or Prescription Solutions, provides pharmacy benefit management services to its plans throughout the United States. Rx, or Prescription Solutions, advertise and provide information to healthcare providers and their plan participants, correspond with healthcare practitioners including but not limited to physicians and pharmacists in the State of Florida, and the general public through the Internet. Rx or Prescription Solutions' Website is accessible by all Florida residents, and residents in Seminole County, Florida. Rx or Prescription Solutions intend and expect Florida residents to access and utilize their Websites in Florida. UHF advertises and provides information to healthcare providers in the State of Florida, their Plan participants, and the general public, through the Internet. UHF's Website is accessible by Florida residents, and residents in Seminole County, Florida. The Defendants intend and expect Florida residents to access and utilize their Websites in Florida. The Defendant, UHG of Minnetonka, Minnesota, owns and operates their fully integrated healthcare companies, such as UHF and Rx or

Prescription Solutions. UHG conducts all their Florida healthcare business and prescription pharmacy management through UHF. UHG conducts much of its pharmacy benefit management services in the State of Florida and nationwide through its subsidiary, Rx or Prescription Solutions.

9. The Defendant, UHF, by its own Website maintains a Pharmacy and Therapeutics Committee which determines the preferred drug list or formulary for UHF.

10. The Defendant, UHF insures patients in the State of Florida, and specifically in Seminole County, Florida including State employees based in Seminole County, Florida, most notably at the Seminole County Courthouses. UHG and UHF also operate many plans whose pharmacy benefit manager is Rx or Prescriptions Solutions.

11. UHG, through its wholly owned subsidiary UHF, and Rx or Prescription Solutions, determines the drug a pharmacist may dispense and be reimbursed on. UHG through its same subsidiaries determines what drug a participating physician treating its plan participants may prescribe.

12. UHF decides which prescriptions that are written by physicians and dispensed by pharmacists in the State of Florida are covered for reimbursement payments.

13. UHG supplies over 50% of the corporate directors for UHF and Rx or Prescription Solutions.

14. UHG operates entirely in the State of Florida through its affiliate, UHF.

15. The companies of UHF and Rx or Prescription Solutions are in fact the alter egos of UHG of Minnetonka, Minnesota. UHG sets the general policy decisions, participates in many of the major decisions, supplies capital, reaps profits from, and in general provides services for fully integrated healthcare operations represented in

Florida by UHF, and the pharmacy benefit management services of Rx or Prescription Solutions.

16. UHF, as the payor with information from its own Website in Section 5F, states that it employs a pharmacy and therapeutics committee which reviews drugs for preferred inclusion on its PDL or preferred drug list. Therefore, UHF fully participates in any prescription decisions made by its pharmacy benefit managers, including Rx or Prescription Solutions. As payor, UHF directs the decisions of its PBM, Rx or Prescription Solutions. The ultimate and final authority rests with UHF and UHG.

17. Rx or Prescription Solutions can fill no prescriptions without payment being authorized by a UHG company, which in the State of Florida is UHF. In essence, any correspondence generated by Rx or Prescription Solutions for patients in the State of Florida is with the full knowledge of the underlying payor, in this case UHF in Florida and UHG nationwide.

III. General Allegations

18. Florida Statute 465.025 clearly states that a pharmacist may not substitute a generic drug unless it is (a) approved or (b) substitutable by the FDA as listed in its Reference Orange Book. Additionally, one drug cannot be substituted for another if those drugs are not both indicated for the same exact medical condition or disease state.

19. UHG through its wholly owned subsidiaries, UHF and Rx or Prescription Solutions, is doing just that. UHG through its subsidiary organizations has coerced Florida physicians and pharmacists into prescribing and dispensing non-therapeutic equivalent or non-bioequivalent pharmaceuticals in place of *Derma-Smoothe/FS® (Body Oil)*. This is accomplished by

correspondence to Florida physicians and pharmacists and physicians and pharmacists throughout the country.

20. For example, in two letters on or about May 24, 2006 and a letter on or about August 15, 2007, pharmacists, physicians and patients were misappropriately informed that there existed a substitute to *Derma-Smoothe/FS® (Body Oil)* for patients with widespread atopic dermatitis/eczema. Many more of this type of letter and conduct are expected to be developed during discovery.

21. Because no other drug has been approved by the FDA as being a therapeutic equivalent, bioequivalent or generic substitute, there can be no legal substitutions for *Derma-Smoothe/FS® (Body Oil)*. Additionally, since no other drug is indicated (specific drug approved to treat a specific medical condition) for use in widespread atopic dermatitis/eczema for patients three (3) months and older with 50% to 90% of body involvement there can be legally no other product medically substituted.

22. Furthermore, there is no generic equivalent product approved by the FDA for *Derma-Smoothe/FS® (Body Oil)*. Thus, any alternative prescription recommended is not a bioequivalent or therapeutic equivalent product to *Derma-Smoothe/FS® (Body Oil)* and cannot be substituted or represented as such. Any action to substitute this product is illegal because it constitutes a misrepresentation of HDI's product, and illegally modifies and interferes with the prescribed treatment of the healthcare provider.

23. It is inappropriate and illegal for any managed care organization to suggest any alternatives that are not bioequivalent or therapeutically equivalent to *Derma-Smoothe/FS® (Body Oil)* and/or refuse to cover HDI's medication when it is medically necessary. No other fluocinolone acetonide (active chemical ingredient)

formulation or, for that matter, any other topical corticosteroid can be legally interchanged and dispensed when a prescription is written for *Derma-Smoothe/FS® (Body Oil)*. The purpose of these letters by Defendants, and their effect, are to mislead physicians, pharmacists and plan members into believing that an effective alternative drug to *Derma-Smoothe/FS® (Body Oil)* can be used when over 50% to 90% of the body is involved with the disease. This, in fact, is not true, and Defendants know it, yet intentionally attempt to substitute non-bioequivalent drugs for HDI's product.

24. Because UHG's employees make up over 50% of the Board of Directors for UHF, and a large portion of the directors for Rx or Prescription Solutions, UHG also derives large percentages of its profits from UHF, and in order to assure economies of scale, shares resources with UHF and Rx or Prescription Solutions. Consequently, UHF and Rx or Prescription Solutions are merely alter-ego corporations of UHG. Therefore, the actions taken by UHF and Rx or Prescription Solutions can be directly attributable to its parent corporation, UHG. The actions of UHG, UHF and Rx or Prescription Solutions violate Florida drug law, mislead and confuse physicians, pharmacists and patients (members), which diminishes the sales of HDI as the misleading communications of all three Defendants persuade Florida pharmacists, physicians, healthcare providers, and patients (members) that other non-therapeutically equivalent or non-generic drugs can be substituted for *Derma-Smoothe/FS® (Body Oil)*.

IV. Statement of the Facts

25. HDI is a pioneer manufacturer and marketer of several dermatologic products for which it owns a new drug application (NDA).

26. HDI owns the NDA for *Derma-Smoothe/FS® (Body Oil)* and HDI is approved to market it under NDA

No. 19-452, which is the FDA referenced drug for widespread atopic dermatitis/eczema. *Derma-Smoothe/FS® (Body Oil)* is the only low potency topical corticosteroid that has been granted a full NDA approval for the specific indications of atopic dermatitis/eczema in children ages three months and above, and adults with as much as 90% body involvement. *Derma-Smoothe/FS® (Body Oil)* is the only topical corticosteroid product that has been demonstrated through clinical studies not to cause adrenal suppression.

27. On or about February 21, 2007 HDI learned of correspondence from Rx or Prescription Solutions that improperly denied patients *Derma-Smoothe/FS® (Body Oil)* and illegally informed patients and physicians who were appropriately prescribing and prescribed *Derma-Smoothe/FS® (Body Oil)* that there existed the medically inappropriate alternatives of triamcinolone, clobetasol, or hydrocortisone creams, ointments and lotions to treat atopic dermatitis/eczema. These letters or correspondences were sent to physicians, pharmacists and plan members. Two of the letters, presently known, were dated May 24, 2006 and one August 15, 2007. At this point, the names of the physicians, pharmacists and patients must be withheld due to HIPAA regulations.

28. The correspondence of Rx or Prescription Solutions on behalf of UHF and UHG clearly states:

> Based on the information provided by you or your physician, you do not meet the established medical necessity criteria or guidelines for *Derma-Smoothe/FS® (Body Oil)* at this time. *Derma-Smoothe/FS® (Body Oil)* is denied. This drug is not on our formulary, coverage requires a contraindication, failure or intolerance to the

following formulary agents: triamcinolone, clobetasol, or hydrocortisone.

29. The correspondence of Rx or Prescription Solutions on behalf of UHF and UHG also stated:

> *Derma-Smoothe/FS® (Body Oil)* is not on our formulary, coverage requires a contraindication, failure or intolerance to all of the formulary agents: clobetasol, triamcinolone, and hydrocortisone. Based on the clinical information provided, a trial on triamcinolone and hydrocortisone is required.

30. Nothing could be further from the truth. This correspondence, in fact, tells physicians and pharmacists that triamcinolone, clobetasol or hydrocortisone are safe to use on patients with up to 90% body involvement. This is false information as widespread use of these agents would cause adrenal suppression. *Derma-Smoothe/FS® (Body Oil)* is the only topical corticosteroid product that has been demonstrated through clinical studies not to cause adrenal suppression after widespread usage. Moreover, at said time, HDI learned that Rx or Prescription Solutions was denying coverage of *Derma-Smoothe/FS® (Body Oil),* yet was willing to cover what was being incorrectly termed "substitutable" for the brand named drug. Additionally, Rx or Prescription Solutions at the direction of UHG, and specifically in the State of Florida at the direction of UHF, have been communicating with healthcare providers notifying them by mail directly in an effort to coerce them to change their patients' prescriptions from the product, *Derma-Smoothe/FS® (Body Oil).* HDI normally does not learn of this conduct, which is believed to be widespread as discovery will show.

31. The action taken by the Defendants to deny this coverage and mislead physicians and pharmacists into believing a properly substituted product exists when it does

not, forces an illegal substitution for this type of disease and treatment.

32. Managed care organizations are required to cover *Derma-Smoothe/FS® (Body Oil)* if they treat and/or cover atopic dermatitis or eczema in patients age three (3) months and above with widespread or up to 50% to 90% of body involvement. There are no products which can be substituted for *Derma-Smoothe/FS® (Body Oil)* in this patient population. *Derma-Smoothe/FS® (Body Oil)* is the only topical corticosteroid product that has been demonstrated through clinical studies not to cause adrenal suppression. In widespread use, no other pharmaceutical can be safely substituted for *Derma-Smoothe/FS® (Body Oil).* Other pharmaceuticals mentioned in Rx or Prescription Solutions' letters that would be used by patients on a widespread area of atopic dermatitis/eczema, according to their FDA approved label and package insert, would cause adrenal suppression. The conduct by Defendants jeopardizes the public health and safety.

33. The unique oil delivery system of *Derma-Smoothe/FS® (Body Oil)* prevents a greater amount of corticosteroid than is therapeutically necessary from systemically entering the patient. Consequently, this prevents adrenal suppression. Triamcinolone or clobetasol or hydrocortisone cannot make this same claim on widespread usage. Their own labeling indicates the danger of adrenal suppression.

34. The information being disseminated by Rx or Prescription Solutions is, therefore, false and has a great potential to harm patients as they are intentionally being deterred from purchasing and/or using *Derma-Smoothe/FS® (Body Oil).* In light of the false information, patients will use less safe and efficacious products.

35. As a result of these and other letters sent by Rx or Prescription Solutions, pharmacists, physicians and

patients are being led to believe that there is an appropriate substitute for *Derma-Smoothe/FS® (Body Oil)*. Therefore, HDI is being, and has been, economically damaged, as well as having the value of its product irretrievably harmed. Rx or Prescription Solutions at the direction of UHG and UHF, has damaged HDI economically and has disparaged HDI's product, good name and reputation. More importantly, Rx or Prescription Solutions, at the direction of UHG and UHF, have jeopardized patient safety by denying coverage of *Derma-Smoothe/FS® (Body Oil)*. Neither patients nor physicians can be forced to try other drugs that are unproven, potentially dangerous and/or are not effective in treating atopic dermatitis or eczema, merely because other drugs are covered by Rx or Prescription Solutions or UHF or ultimately UHG in their integrated healthcare system. As a direct and proximate result of Rx or Prescription Solutions' unlawful, deceptive, misleading labeling and/or advertising, HDI has suffered and continues to suffer irreparable loss and injury.

36. As a direct and proximate result, Rx or Prescription Solutions, at the direction of UHF and UHG's unlawful, deceptive, and misleading advertising, HDI's good name and reputation have be libeled, slandered and/or disparaged. Specifically, the Defendants have and continue to disseminate and/or publish false statements that induce potential *Derma-Smoothe/FS® (Body Oil)* users and/or purchasers to believe that *Derma-Smoothe/FS® (Body Oil)* is not the only drug available for the treatment of atopic dermatitis/eczema in pediatrics three (3) months and older and adults with up to 50% to 90% body involvement, and that there are other drugs that can be used on widespread atopic dermatitis safely, and that there are generic versions of *Derma-Smoothe/FS® (Body Oil)*. This has resulted in economic damages to HDI, included but not limited to, lost sales, lost profits, and

diminution of value of its intellectual property ownership of its NDAs.

37. All conditions precedent to the filing of this lawsuit have been satisfied, met or waived.

COUNT I

PRELIMINARY INJUNCTION/TEMPORARY RESTRAINING ORDER

38. HDI realleges and incorporates by reference the allegations contained in paragraphs 1 through 37 of the Amended Complaint as if fully set forth herein.

39. This is an action for temporary injunctive relief.

40. Rx or Prescription Solutions have disseminated and/or published and continue to disseminate and/or publish false, misleading, deceptive, libelous and/or defamatory statements, advertisements, correspondence and/or representations, regarding HDI's product, *Derma-Smoothe/FS® (Body Oil)*.

41. In light of Rx or Prescription Solutions' tortious acts and the tortious acts of UHF as payor and UHG as final authority and parent organization, HDI suffers and will continue to suffer economic damages and, more importantly, damage to its reputation and intellectual property for which there is no adequate remedy at law. The value of HDI's products and its innovative reputation will continue to be diminished by the Defendants' actions.

42. Despite HDI's requests to cease and desist this continuing tortious activity, Defendants continue to disseminate and/or publish these false, misleading and defamatory statements.

43. Unless Rx or Prescription Solutions is restrained and enjoined from disseminating correspondence that misleads physicians and pharmacists into believing that there is a substitute pharmaceutical for

Derma-Smoothe/FS® (Body Oil), this false, misleading, deceptive, libelous and defamatory information regarding *Derma-Smoothe/FS® (Body Oil)* will continue and HDI will continue to suffer permanent, severe and irreparable harm that will lead to the complete and unfounded destruction of its reputation in Florida and nationally.

44. HDI has a clear legal right to relief on its claims for damages based on Defendants' violation of various state causes of action, including, but not limited to, Florida's Deceptive and Unfair Trade Practices Act, misleading advertising, Fla. Stat. § 817.41, injurious falsehood and defamation.

45. Unless UHF, UHG and Rx or Prescription Solutions are restrained and enjoined from disseminating and/or publishing this false, misleading, deceptive, libelous and defamatory information regarding *Derma-Smoothe/FS® (Body Oil)*, HDI will continue to suffer permanent, severe and irreparable harm.

46. The issuance of an injunction will serve the public interests as it will prevent the dissemination of false and misleading information that could lead to harm of Florida residents as this information will result in the prescription purchase and use of drug products without the proven safety and efficacy of *Derma-Smoothe/FS® (Body Oil)* for their specific indications.

47. In addition, in light of Rx or Prescription Solutions' tortious acts under the direction of UHF and UHG as outlined above, patients will forego or avoid the purpose and/or use of *Derma-Smoothe/FS® (Body Oil)*, which would likely be beneficial to their specific disease entity.

WHEREFORE, HDI specifically requests this Court temporarily and permanently enjoin the Defendants from disseminating and/or publishing the false, misleading,

deceptive, libelous and/or defamatory information outlined above regarding *Derma-Smoothe/FS® (Body Oil)*.

COUNT II

INJURIOUS FALSEHOOD

48. HDI realleges and incorporates by reference the allegations contained in paragraphs 1 through 37 of the Amended Complaint as if fully set forth herein.

49. Rx or Prescription Solutions, through its two correspondences of May 24, 2006 and again on August 15, 2007, have disseminated and continue to disseminate other false, misleading, deceptive and/or defamatory information, regarding *Derma-Smoothe/FS® (Body Oil)*. This is done at the direction, and with the permission of, UHF and parent company, UHG. Specifically, regarding *Derma-Smoothe/FS® (Body Oil)* prescriptions that Rx or Prescription Solutions approve or disapprove by the pharmacy benefit management, UHF then approves or disapproves the payment reimbursement, and UHG condones and participates in these pharmacy benefit management and reimbursement decisions, fills or arranges to fill or reimburses or arranges to reimburse for the Defendants who have improperly suggested alternatives that are not bioequivalent or therapeutically equivalent of *Derma-Smoothe/FS® (Body Oil)*.

50. Any suggestions that there exists any generic equivalent of *Derma-Smoothe/FS® (Body Oil)* constitute an injurious falsehood on the part of the Defendants, which has caused damage to HDI and loss of income and revenues for *Derma-Smoothe/FS® (Body Oil)*.

51. The Defendants' affirmative suggestion of a non-indicated equivalent contains false information, as published clinical studies indicate. This was done through the correspondence of Rx or Prescription Solutions at the direction of payor, UHF, and parent company, UHG.

52. This false, misleading and/or defamatory information was disseminated and/or communicated to physicians in the State of Florida, including but not limited to, Florida physicians, pharmacists and residents in letters dated May 24, 2006 and August 15, 2007. Discovery is expected to uncover many, many more examples.

53. Defendants knew or should have known that the false, misleading and/or defamatory information was likely to influence Florida residents, namely perspective healthcare providers, prescribers, and/or users of *Derma-Smoothe/FS® (Body Oil).*

54. The false, misleading and/or defamatory information in the correspondences of Rx or Prescription Solutions, at the direction of UHF and UHG, has played, and continues to play, a material and substantial role in inducing Florida residents, and residents throughout the country, namely prescribers, patients and/or Defendants' pharmacy benefit plan participants, to purchase and/or use drugs other than *Derma-Smoothe/FS® (Body Oil),* and/or come to the false belief that there are alternatives to *Derma-Smoothe/FS® (Body Oil).* This conduct by the Defendants has been intentional, willful and undertaken with malice.

WHEREFORE, as a direct and proximate result of these publications, dissemination and/or communication of Defendants' false, misleading, deceptive and/or defamatory statements, HDI has suffered compensatory damages, including but not limited to, general, special, consequential, incidental, lost profits, lost revenues, diminution in the value of the product and the valuation of HDI's reputation.

COUNT III
DEFAMATION

55. HDI realleges and incorporates by reference the allegations contained in paragraphs1 through 37 of the Amended Complaint as if fully set forth herein.

56. This is an action for defamation.

57. Rx or Prescription Solutions is affirmatively disseminating that there are other fluocinolone acetonide formulations and other corticosteroid products that demonstrate the bioequivalence and/or therapeutic equivalence to *Derma-Smoothe/FS® (Body Oil).* Rx or Prescription Solutions, at the direction of UHF and UHG, have specifically by their actions implied that they are bioequivalent and/or therapeutically equivalent to *Derma-Smoothe/FS® (Body Oil).* There are no other fluocinolone acetonide formulations or corticosteroid products which have demonstrated bioequivalence or therapeutic equivalence to *Derma-Smoothe/FS® (Body Oil).* Other products are not indicated for, and contain specific warnings against, using the product when 50% to 90% of the patient's bodies are involved. Consequently, no other fluocinolone acetonide formulation or any other topical corticosteroid products can be legally interchanged with *Derma-Smoothe/FS® (Body Oil).* There is no generic for *Derma-Smoothe/FS® (Body Oil).* Rx or Prescription Solutions intentionally and with malice have printed, published, and/or circulated, and UHF and UHG have caused to be printed, published and/or circulated, statements and information, stating that there are bioequivalent and/or therapeutic equivalents when presented with *Derma-Smoothe/FS® (Body Oil)* prescriptions.

58. The publication of such defamatory information to third parties, including the doctors who received correspondence on May 24, 2006, and the pharmacists who received correspondence on August 15, 2007, has injured HDI in that healthcare providers,

patients, plan participants of the Defendants, and the general public have been provided false information as to the safety of *Derma-Smoothe/FS® (Body Oil).* As such, these healthcare providers avoided prescribing *Derma-Smoothe/FS® (Body Oil).* Moreover, patients also avoid purchasing and/or implementing *Derma-Smoothe/FS® (Body Oil).* These tortious actions by Rx or Prescription Solutions affirmatively, and at the direction of UHF and UHG, as described above, have and will deter healthcare providers, prescribers, patients, plan participants of the Defendants, and general consumers from associating and/or doing business with HDI.

59. The unprivileged dissemination, communication and/or publication of such defamatory information by the Defendants have, and continue to induce, healthcare proprietors/prescribers, plan participants of UHF and UHG, patients and/or consumers to avoid prescribing and/or purchasing *Derma-Smoothe/FS® (Body Oil).*

60. These false and misleading correspondences have induced physicians to prescribe other products, pharmacists to fill other products, and patients or members of UHF to purchase and use other products that are not indicated for the widespread disease of atopic dermatitis/eczema.

WHEREFORE, as a direct and proximate cause of Rx or Prescription Solutions' correspondence and the actions of UHF and UHG in this unprivileged dissemination, communication and/or publication of the above-referenced defamatory information, HDI has suffered and continues to suffer compensatory damages, including but not limited to, general, special, consequential, incidental, lost profits, lost revenues, diminution in the value of product, and diminution in the

value of HDI's reputation to the general consumer and the national pharmaceutical community.

COUNT IV

MISLEADING ADVERTISING, FLA. STAT. § 817.41

61. HDI realleges and incorporates by reference the allegations contained in paragraphs 1 through 37 of the Amended Complaint as if fully set forth herein.

62. This is an action against the Defendants for violation of Fla. Stat. § 817.41, prohibiting misleading advertising. Rx or Prescription Solutions is affirmatively suggesting the improper substitution of other drugs in their correspondences of May 24, 2006 and August 15, 2007, consisting of triamcinolone, clobetasol, and hydrocortisone.

63. Rx or Prescription Solutions is affirmatively misrepresenting HDI products to pharmacists, as well as those receiving prescriptions, by suggesting that other products are appropriate therapeutic substitutions for *Derma-Smoothe/FS® (Body Oil),* when clearly they are not. Rx or Prescription Solutions, at the direction of UHF and UHG, is affirmatively misrepresenting HDI products to physicians as well as those receiving prescriptions by suggesting that other products are appropriate therapeutic substitutions for *Derma-Smoothe/FS® (Body Oil),* when clearly they are not.

64. HDI's product, *Derma-Smoothe/FS® (Body Oil),* and its predecessor compounds, have been proven through well documented published clinical studies dating back to the mid-1980's, to be safe and effective for patients with widespread atopic dermatitis/eczema.

65. Rx or Prescription Solutions, at the direction of UHF and UHG, have violated Fla. Stat. § 817.41, by publishing and/or disseminating false information concerning the safety of *Derma-Smoothe/FS® (Body Oil)* to physicians, pharmacists and the public in general, to

UHF's plan participants located in the State of Florida and to UHG's plan participants located across the country, as well as to healthcare providers, both in Florida and nationally. Correspondence of August 15, 2007, clearly directs a pharmacy not to fill a prescription of *Derma-Smoothe/FS® (Body Oil).* This is in addition to the correspondence of May 24, 2006 directing physicians that they cannot prescribe *Derma-Smoothe/FS® (Body Oil).*

66. By virtue of Rx or Prescription Solutions', at the direction of UHF and UHG, affirmative misleading representations, members, patients and physicians are being forced to try other drugs that are unproven, potentially hazardous, and/or not effective in treating widespread atopic dermatitis/eczema on up to 50% to 90% of their body, merely because they are covered by UHF's medical plans, Rx or Prescription Solutions' pharmacy benefit management procedures, and/or UHG's national PDL.

67. There are representations that Rx or Prescription Solutions, at the direction of UHF and UHG, is disseminating in regards to *Derma-Smoothe/FS® (Body Oil)* prescriptions as information which is known, or through the exercise of reasonable care of highly experienced pharmacy benefit managers and highly experienced healthcare plan administrators and operators, could definitely have been ascertained to be untrue and misleading, and which was made or disseminated with the intent or purpose, either directly or indirectly, of selling products or services to induce the general public, healthcare providers and/or prescribers, as well as Florida residents and plan participants to avoid the use of *Derma-Smoothe/FS® (Body Oil).*

68. Such statements in the form of advertisements and/or representations, as identified above, constitute untrue and misleading statements. Specifically,

Defendants knowingly misrepresented material facts concerning the safety and efficacy of *Derma-Smoothe/FS® (Body Oil)* by advertising to physicians, pharmacists and patient members that there are bioequivalent or therapeutically equivalents of *Derma-Smoothe/FS® (Body Oil)* available to patients and/or prescribers.

69. That the physicians contacted by correspondence, pharmacists and members of UHF and UHG plans were intentionally induced to prescribe, dispense and purchase other products than their original *Derma-Smoothe/FS® (Body Oil)* prescriptions which were written.

WHEREFORE, as a direct and proximate result of Rx or Prescription Solutions' actions, at the direction of UHF and UHG as identified above, HDI has suffered and continues to suffer damages, including but not limited to, general, special, consequential, incidental, lost profits, lost revenues, diminution in value of *Derma-Smoothe/FS® (Body Oil),* and devaluation of HDI's reputation with the general public, healthcare providers/prescribers, as well as the Florida and national pharmaceutical community.

COUNT V
DECEPTIVE AND UNFAIR TRADE PRACTICES ACT, FLA. STAT. § 501.201, *ET SEQ.*

70. HDI realleges and incorporates by reference the allegations contained in paragraphs 1 through 37 of the Amended Complaint as if fully set forth herein.

71. This action is brought against Rx or Prescription Solutions and UHG pursuant to Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq.* HDI has standing to bring this action pursuant to Fla. Stat. § 501.203(6) and § 501.211(1). UHF, as a defendant under the regulation of the Florida Department of Insurance or currently the Department of Financial Regulation, is not complying with these

regulations pursuant to this Count. Rx or Prescription Solutions, under the direction of UHG, has communicated and disseminated, and continues to communicate and disseminate false and misleading information. Specifically, Rx or Prescription Solutions knowingly misrepresented material facts concerning the safety and efficacy of *Derma-Smoothe/FS® (Body Oil)* in its correspondences on March 24, 2006 and August 15, 2007. The correspondence of Prescription Solutions clearly states as referenced earlier that *Derma-Smoothe/FS® (Body Oil)* is not on their formulary and coverage requires a contraindication, failure or intolerance to the following formulary agents: triamcinolone, clobetasol or hydrocortisone. These statements were intentionally used to lead physicians, pharmacists and residents of the State of Florida as plan members to believe that there are bioequivalent or therapeutic equivalents of *Derma-Smoothe/FS® (Body Oil)* available to patients and/or prescribers in Florida and elsewhere.

72. Rx or Prescription Solutions, as an expert in the field of pharmacy benefit management with a staff of pharmacists and physicians, clearly knows that only *Derma-Smoothe/FS® (Body Oil)* has been proven through well documented, published clinical studies to be safe and effective in the widespread use for atopic dermatitis/eczema where 50% to 90% of the patient's body is involved. Therefore, *Derma-Smoothe/FS® (Body Oil)* has no bioequivalent equivalent or therapeutic equivalent, and as such *Derma-Smoothe/FS® (Body Oil)* is required to be dispensed in plans pharmacy benefit managed by Rx or Prescription Solutions when the drug is prescribed in those particular indications.

73. Rx or Prescription Solutions knowingly misrepresented and misled healthcare providers/prescribers, the public in general, and Florida plan participants for whom Rx or Prescription Solutions

manages the pharmacy benefit management in particular, by disseminating, communicating and/or publishing statements, representations and/or information that was false and misleading in their correspondences as referenced above.

74. Rx or Prescription Solutions has, and continues to, intentionally and willfully disseminate, communicate and/or publish this false and misleading information.

75. Rx or Prescription Solutions induced, and continues to induce, Florida and national healthcare providers/prescribers, Florida plan participants, and the public in general to believe that there are bioequivalent and/or therapeutic equivalents available to *Derma-Smoothe/FS® (Body Oil).* The Defendants' actions, as outlined above, can be proven to have offended public policy and are substantially injurious to HDI, as well as to the public in general and Florida plan participants in general. Rx or Prescription Solutions, by inducing healthcare providers, Florida plan participants, and the public in general to forego and/or avoid the purpose and/or use of *Derma-Smoothe/FS® (Body Oil)* by disseminating false information throughout the State of Florida violates Fla. Stat. § 501.201, *et seq.*, among other statutes and common law.

WHEREFORE, Plaintiff, HDI, demands judgment in its favor, including attorneys' fees for having to bring this action for Defendants' violation of the above-mentioned Florida Statutes.

COUNT VI
PRODUCT DEFAMATION

76. HDI realleges and incorporates by reference the allegations contained in paragraphs 1 through 37 of the Amended Complaint as if fully set forth herein.

77. This is an action for product defamation or diminution of the value of the product brand and trade name. Rx or Prescription Solutions, at the direction of UHF and UHG, has made and continues to make false and/or misleading statements in correspondence in the form of statements advising physicians, pharmacists and/or plan members and participants that there are adequate or equivalent substitutes for *Derma-Smoothe/FS® (Body Oil).* Specifically, the letters in question advise physicians, pharmacists and/or UHF and UHG's plan participants that persons with widespread atopic dermatitis/eczema could safely use another product without incurring adrenal suppression as a side effect. This statement is false and misleading, as *Derma-Smoothe/FS® (Body Oil)* has been the only product proven by clinical trials not to cause adrenal suppression.

78. The false and misleading information disseminated and/or published by the Defendants has the capacity to deceive consumers of *Derma-Smoothe/FS® (Body Oil),* which consumers include physicians, pharmacies, plan members and patients, as said false and misleading information implies that other products are safe for persons with widespread atopic dermatitis/eczema, with 50% to 90% body involvement.

79. The Defendants' intentional deception as outlined above, has had and will continue to have a material effect on the brand name and trade package of *Derma-Smoothe/FS® (Body Oil)* as a product.

80. Rx or Prescription Solutions', at the direction of UHF and UHG, intentional deception, as outlined above, has had and will continue to have a direct effect on the product financially.

81. As a result of Rx or Prescription Solutions' false and misleading advertising, at the direction of UHF and UHG, *Derma-Smoothe/FS® (Body Oil)* as a product

has been and continues to injure HDI from a financial perspective, as well as sustaining substantial injury to its brand name and trade product. Rx or Prescription Solutions' false and misleading statements, disseminated and/or published in the form of letters sent to physicians, patients and pharmacists, misrepresent the inherent quality and characteristic of this product in that these correspondences deceive consumers into thinking that this product can be replaced by other products mentioned in the correspondences, when in fact, the opposite is true.

82. As such, *Derma-Smoothe/FS® (Body Oil)* has suffered and continues to suffer damages, including but not limited to, general, special, consequential, incidental, lost profits, lost revenues, diminution in the product and the devaluation of *Derma-Smoothe/FS® (Body Oil's)* good brand name and reputation.

WHEREFORE, as a direct and proximate result of the Defendants' actions, as outlined above, HDI has suffered and continues to suffer damages, including but not limited to, general, special, consequential, incidental, lost profits, lost revenues, diminution in the value of *Derma-Smoothe/FS® (Body Oil)* and devaluation of HDI's reputation with healthcare providers, the general public, and the national healthcare community.

DEMAND FOR JURY TRIAL

HDI hereby demands trial by jury on all issues so triable against the Defendants.

RESPECTFULLY SUBMITTED this 20th day of February, 2008.

/s/ Larry M. Roth
Larry M. Roth, Esquire
Florida Bar No. 208116
Neil P. Di Spirito, Esquire
Florida Bar #: 0027698
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Telephone: 407-872-2239
Facsimile: 407-872-6927
Attorneys for Plaintiff,
Hill Dermaceuticals, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 20, 2008, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF System which will send a Notice of Electronic Filing to: Edmund O. Loos III, Esquire and Amanda L. Chapman, Esquire, GREENSPOON MARDER, P.A., Capital Plaza I, Suite 500, 201 East Pine Street, Orlando, FL 32801 and a copy furnished by electronic mail to William A. Davis, Esquire, and Noam Fischman, Esquire, MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C., 701 Pennsylvania Avenue, NW, Washington, DC 20004-2608 (wadavis@mintz.com).

/s/ Larry M. Roth
Larry M. Roth, Esquire
Florida Bar No. 208116

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UNITED STATES DISTRIC COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

HILL DERMACEUTICALS, INC., a Florida corporation,	
Plaintiff,	
v.	**Case No. 6:07-2032-Orl-31 GJK**
Rx SOLUTIONS, also known as PRESCRIPTION SOLUTIONS CORPORATION, a foreign corporation, UNITED HEALTHCARE COMPANY, PACIFIC HEALTH SYSTEMS, a foreign corporation, and UNITED HEALTHCARE OF FLORIDA, a Florida corporation,	
Defendants.	

DEFENDANTS' MOTION AND MEMORANDUM OF POINTS AND AUTHORITIES FOR RECONSIDERATION, OR ALTERNATIVELY, FOR THIS COURT TO VACATE ITS REMAND ORDER DATED FEBRUARY 25, 2008 AND 3.01(G) CERTIFICATION

Served Defendants, Rx Solutions, also known as PRESCRIPTION SOLUTIONS CORPORATION, a foreign corporation and UNITED HEALTHCARE OF FLORIDA, a

Florida corporation (collectively "Defendants"), by and through undersigned counsel and pursuant to M.D.L.R. 3.01, hereby file this Motion for Reconsideration, or Alternatively, for This Court to Vacate Its Remand Order Dated February 25, 2008.

On February 5, 2008, the Court dismissed Plaintiff's complaint (docket #23). The dismissal was without prejudice. The Court provided Plaintiff with an opportunity to amend its complaint by February 20, 2008, to comply with Fed.R.Civ.P. 8 and 9.

Shortly before the Court dismissed the complaint, Plaintiff filed a motion to remand. Defendants' opposition to the motion to remand was due February 15, 2008. But once the Court dismissed Plaintiff's complaint, defense counsel believed that the pending motion for remand effectively was moot, at least until Plaintiff filed an amended complaint complying with the order of dismissal. Absent an operative complaint on file with this court, Defendants' arguments for or against remand would have been speculative. Defense counsel did not and could not know what factual allegations and what causes of action, or even what parties, would appear in Plaintiff's amended complaint.

On February 20, 2008, Plaintiff filed an amended complaint. Defense counsel contacted opposing counsel to discuss the motion to remand. On Friday, February 22, 2008, counsel agreed that Plaintiff would file a short Notice to the Court renewing its prior motion to remand based on the newly-filed amended complaint. The parties also agreed that Defendants would have fourteen days, based on local rules, to oppose Plaintiff's motion to remand. In fact, defense counsel was drafting a stipulation so stating when the Court issued its Order dated February 25, 2008, remanding this case. In hindsight, it appears that defense counsel would have been better served by filing a Notice

with the Court on or before February 15, 2008, stating its understanding for the record that the remand motion was moot or no longer ripe for adjudication.

For these reasons, and as further explained below, there is good cause for this Court to vacate its remand order, and principles of equity dictate that result as well. Defendants also respectfully request that the Court permit them an additional ten days to oppose Plaintiff's remand motion, enabling the Court to decide the remand issue on the merits of the parties' respective papers.

In further support of this Motion, Defendants sate as follows:

1. The Court remanded this case on February 25, 2008, finding that Defendants did not oppose Plaintiff's motion to remand this case to state court. As stated above, while Defendants do, in fact, oppose remand, Defendants did not file their memorandum opposing the motion absent an operative complaint. Defendants' reasonably believed that Plaintiff's remand motion effectively had rendered moot by this Court's order dismissing the Complaint.

2. Plaintiff moved to remand this case to state court on or about January 30, 2008. According to the Court's ECF system, Defendants' opposition to this motion was due on or before February 15, 2008.

3. On February 5, 2008, less than a week after Plaintiff filed its remand motion, the Court dismissed Plaintiff's Complaint in its entirety, without prejudice. Without an active Complaint pending, Defendants did not oppose Plaintiff's remand motion. Defendants reasonably believed that the Court's dismissal of this case effectively rendered Plaintiff's remand motion moot.

4. In addition to mootness concerns, Defendants did not believe that the Court's resources and the parties' resources would be used effectively by drafting and filing a memorandum of law with no pending operative complaint.

Defendants could not have known on or before February 15, 2008, what facts and what causes of action would be contained in Plaintiff's amended complaint, or even what parties would remain. Nor could Defendants have known for sure whether Plaintiff would file an amended complaint. As a result, there was a considerable chance that Defendants' arguments opposing remand with respect to the original complaint would be different than those applicable to the newly-filed amended complaint.

5. Plaintiff and Defendant had the same understanding about the procedural posture of this case. Two days after Plaintiff filed its Amended Complaint, on Friday, February 22, 2008, Defendants' counsel contacted Plaintiff's counsel to discuss how this case should proceed procedurally. During this call, Plaintiff's counsel agreed that Plaintiff needed to renew its remand motion, and the parties began negotiating a stipulation to be filed with Court this week. Among the issues the parties sought to address in this stipulation, Plaintiff and Defendants agreed that Plaintiff would re-file its remand motion and Defendants would have a reasonable amount of time to oppose that motion.

6. Moreover, even setting aside the reasonableness of Defendants' belief that Plaintiff's remand motion had been rendered moot, equity also requires that Defendants be accorded the opportunity to oppose a remand here. Though Plaintiff sued a non-diverse defendant—United HealthCare of Florida—Plaintiff has not articulated any reasonable basis for including that Defendant in this case. Plaintiff admits that another defendant, Prescription Solutions, uttered each of the purportedly harmful statements about Plaintiff. Therefore, there is no reason for including United HealthCare of Florida in this case except to defeat diversity fraudulently.

7. Separately, even though Plaintiff delicately avoids alleging a federal cause of action directly, this case inextricably involves issues that require adjudicating the Medicare Modernization Act and the Food, Drug and Cosmetics Act. If the Defendants' third-party communications (the crux of Plaintiff's Amended Complaint) were compliant with these federal laws, then there is no basis for the causes of action pled in the amended complaint. Accordingly, this case requires the adjudication federal questions, compliance with the Medicare Modernization Act and the Food, Drug and Cosmetics Act, and is within the original jurisdiction of this Court.

8. In short, Defendants' bases for removing this case to this Court were significant and complex, and, respectfully, require a fully informed review by this Court.

9. **3.01(g) Certification**: I herby certify that the parties have conferred telephonically about the contents of this motion and could not agree to a resolution.

WHEREFORE, for these reasons, and for any other reasons that the Court deems just, proper, and equitable, Defendants respectfully request that the Court reconsider or otherwise vacate its remand order dated February 25, 2008, grant Defendants ten additional days (to be counted in accordance with local rules and practice) from the date of this Motion to oppose Plaintiff's remand motion, and to grant any additional relief that the Court deems appropriate.

Respectfully submitted,

GREENSPOON MARDER, P.A.
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Email: Edmund.loos@gmlaw.com

By: s/EDMUND O. LOOS III
EDMUND O. LOOS III
Florida Bar No. 899161
AMANDA L. CHAPMAN
Florida Bar No. 176095
-and-
William A. Davis, Esq. (admitted pro hac vice)
Noam B. Fischman, Esq. (admitted pro hac vice)

Mintz Levin Cohn Ferris Glovsky & Popeo, PC
701 Pennsylvania Avneue, N.W.
Washington, D.C. 20004
Telephone: (202) 434-7300
Facsimile: (202) 434-7400

CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of February, 2008, I electronically filed the foregoing Motion and Memorandum of Points and Authorities for Reconsideration, or, Alternatively, for This Court to Vacate Its Court-s Remand Order Dated February 25, 2008, by using the CM/ECF system and I caused a true and I caused a true and correct copy to be served upon counsel of record Neil P. Di Spirito, Esq., Attorney for Plaintiff, Law Offices of Larry M. Roth, P.A., Post Office Box 547637, Orlando, Florida 32854-7637 via the Court's ECF system and by U.S. Mail.

By: s/EDMUND O. LOOS III
EDMUND O. LOOS III
Florida Bar No. 899161
AMANDA L. CHAPMAN
Florida Bar No. 176095

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AFFIDAVIT OF RANDALL COVERMAN, M.D.

BEFORE ME, the undersigned authority on this day personally appeared Randall Coverman, M.D., who, upon his oath duly deposes and states as follows:

1. This Affidavit is made on my own personal knowledge and belief. I am over the age of 18 years, and otherwise *sui juris*. I testify as to the following matters based upon my own personal knowledge.

2. Educational Background – I earned my undergraduate degree from the University of Florida; my medical degree from the University of Miami, School of Medicine; conducted my residency in Dermatology at UCLA; and have practiced medicine in the field of Dermatology in the Orlando, Florida area since 1979.

3. I prescribed Derma-Smoothe/FS Scalp Oil for an adult patient who suffered from the signs and symptoms of scalp Psoriasis. I chose Derma-Smoothe/FS Scalp Oil for the following reasons:

A) Derma-Smoothe/FS Scalp Oil is the only topical corticosteroid that can be used for scalp Psoriasis that does not cause adrenal suppression, as stated in its labeling.

B) The peanut oil vehicle in Derma-Smoothe/FS Scalp Oil softens the crust and scales and adds needed moisture to the entire scalp.

C) When I prescribed Derma-Smoothe/FS Scalp Oil, I intended my patient to use a corticosteroid treatment that would be used once a day, over the entire scalp, for a minimum of 4 hours with the use of a shower cap that is packaged with the product. Other corticosteroids are not approved for use in this manner, as they would cause severe side effects.

D) When I prescribed Derma-Smoothe/FS Scalp Oil, I intended my patient to use a corticosteroid with a proven efficacy record and for my patients to be free of the signs and symptoms of scalp Psoriasis within

approximately three weeks of once-a-day therapy. That is unusually fast and effective result when treating scalp Psoriasis.

E) Rx Solutions responded by stating that it would not cover Derma-Smoothe/FS Body Oil, which is not the medication I prescribed nor intended my patient to receive. I then filled out a prior authorization form for Derma-Smoothe/FS Scalp Oil and the patient was denied coverage again of Derma-Smoothe/FS Body Oil.

4. Rx Solutions wrote the following statement on the denial of coverage letter to the patient:

> We have denied coverage of the following prescription drug(s) that you or your physician requested: DERMA-SMOOTHE/FS BODY OIL.
>
> We denied the request because:
> Based on the information provided by you or your physician, you do not meet the established medical necessity criteria or guidelines for DERMA-SMOOTHE/FS BODY OIL at this time.
>
> DERMA-SMOOTHE IS DENIED. THIS DRUG IS NOT ON OUR FORMULARY. COVERAGE REQUIRES A CONTRAINDICATION, FAILURE OR INTOLERANCE TO THE FOLLOWING:
>
> FORMULARY AGENT(S): TRIAMCINOLINE; CLOBETASOL, OR HYDROCORTISONE. THANK YOU, AKP, PHARM.D.

5. Clobetasol is a super-potent corticosteroid that is well known to cause adrenal suppression and may affect adversely other medications the patient is taking.

6. Triamcinolone and hydrocortisone do not have safety data in their labeling and are not approved for scalp Psoriasis.

7. I prescribed Derma-Smoothe/FS Scalp Oil so I would not have to worry about the aforementioned safety concerns. As a Dermatologist, I make informed decisions for my patients based on the following criteria: my knowledge of medicine; my knowledge of the disease the patient suffers from; the safety profile of the medication (i.e, the absorption rates of the corticoid in question when used over the entire scalp); and how the medications I prescribe may interact with other medications the patient is already taking.

8. Rx Solutions' denial forced me into a position of having to choose a drug other than Derma-Smoothe/FS Scalp Oil, my drug of choice. I would have had to prescribe medications for my patient, against my better judgment, that either 1) may cause adrenal suppression, as stated on the products' labeling; 2) are not indicated for scalp Psoriasis, and 3) have no safety data in their labeling.

9. As I mentioned above in paragraph 3(E), the Derma-Smoothe/FS Scalp Oil was rejected as Derma-Smoothe/FS Body Oil. When I sent this rejection letter to Hill Dermaceuticals, Inc. ("Hill"), it was honestly thought to be a Derma-Smoothe/FS Body Oil rejection. Yesterday, on May 28, 2008, upon further inspection of my records, I informed Hill they were mistaken and the original rejected prescription was for Derma-Smoothe/FS Scalp Oil. Rx rejected it as Derma-Smoothe/FS Body Oil. This honest miscommunication led to Hill believing Derma-Smoothe/FS Body Oil had been rejected in the May 24, 2006 denial letter.

I DECLARE under penalty of perjury that the foregoing is true and correct. Executed on this 30th day of May, 2008.

Further Affiant sayeth not.

s/ Randall Coverman, M.D.

_____

RANDALL COVERMAN, M.D.